



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

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About the Good Clinical Practice (GCP) Inspection Program

Clinical trials of medicines, biologicals and medical devices regulated under the Clinical Trial Notification (CTN) or Clinical Trial Approval (CTA) are subject to the Good Clinical Practice (GCP) Inspection Program. Our GCP inspectors assess whether Australian clinical trial sites are meeting their GCP responsibilities.

GCP is an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials. Compliance with GCP provides assurance that the rights, safety, and well-being of clinical trial participants are protected and that the trial data generated are credible.



We refer to the TGA as 'we', 'us', or 'our' and to clinical trial sites as 'you'. We use 'must' or 'required' to describe something you are **legally obliged** to do. We use 'should' to **recommend** an action that will support you to meet your legal requirements.

Who we inspect

All Australian investigator sites involved in CTN and CTA trials of medicines, biologicals and devices are subject to the GCP inspection program.

Human Research Ethics Committees (HREC) and trial sponsors are not included in the scope of the GCP inspection program. The site Principal Investigator (PI) can invite the sponsor representative(s) to attend the inspection opening and closing meeting. We ask site staff to tell us ahead of time of all attendees, including the sponsor representative(s), so they can be added to the inspection plan that is shared with the inspectee(s).

Any party or organisation contracted to carry out some or all clinical trial-related activities with, or for, the site may be inspected. Our inspectors will confirm the party or organisation can support the site's compliance with Australian clinical trial obligations. Such inspections will typically be arranged through the clinical trial site.

We will avoid duplicating inspections carried out as part of another country's GCP inspection program when feasible. The site and sponsor are not charged for an inspection.

Why we inspect

The GCP Inspection Program aims to strengthen our monitoring activities and protect public health.

GCP inspections allow us to:

- verify you are compliant with the GCP standard(s) and have met your clinical trial responsibilities
- provide education and work with you to ensure you have effective systems in place aligning with Australian legislation and the relevant GCP guideline(s).
- if appropriate, share information relating to the inspection findings to the approving authority (the institutions or organisations where trials are conducted) and/or the approving Human Research Ethics Committee (HREC).

Preparing for an inspection

Know your GCP responsibilities



A GCP inspection may be carried out at any stage of the clinical trial lifecycle from the early phase of participant recruitment to completed trials. Do not wait for an inspection announcement from the TGA to start preparing for an inspection.

All clinical trials carried out under the CTN or CTA schemes must be in accordance with the relevant GCP guideline(s). We recognise the following internationally accepted GCP guidelines:

Medicines and biologicals

- [International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice \(ICH GCP E6\) with TGA annotations.](#)

You should refer to the current version of the ICH GCP E6.

Medical devices

- International Organisation for Standardisation (ISO) 14155 – Clinical Investigation of Medical Devices for Human Subjects – Good Clinical practice (ISO 14155).

You should refer to the current version of ISO 14155. Sites will need to obtain their own copy of ISO 14155 which may incur a cost. We cannot provide a copy of this standard.



In this guidance, references to protocol include:

- Clinical Investigational Plan (CIP) in ISO 14155 for medical devices
- the meaning of protocol in ICH GCP E6 for medicines and biologicals.

Inspectors will examine your compliance with the applicable Australian therapeutic legislation and guideline(s):

- [Therapeutic Goods Act 1989](#) (the Act)
- [Therapeutic Goods Regulations 1990](#) (the Regulations)
- [Therapeutic Goods \(Medical Devices\) Regulation 2002](#) (the Devices Regulations)
- the GCP guideline(s)
- the [National Statement on Ethical Conduct in Human Research Involving Humans](#) (the National Statement).
- the trial-specific protocol and amendments, approved by the relevant HREC.

The inspection process, the type of inspection and the grading of inspection findings is the same for medicines, biologicals and device trials. If your clinical trial involves a medicine or biological **and** a medical device both ICH GCP E6 and ISO 14155 will apply. This includes clinical trials involving a:

- medical device-medicine combination product
- medical device-biological combination product
- medicine and a medical device
- biological and medical device.

Understanding your responsibilities will help you know what is required to meet your GCP obligations.

- The [Australian clinical trial handbook](#) is written in plain English and describes the Australian therapeutic goods legislation relevant to clinical trials. It is a tool to help trial sponsors, HRECs, investigators and approving authorities (institutions) understand their roles and responsibilities under the CTA and CTN schemes.
- The [National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia](#) (National SOP) is endorsed by the TGA and was developed to be consistent with ICH GCP E6 and the National Statement on Ethical Conduct in Human Research. You will find procedures and templates for key clinical trials activities for medicines, biologicals and devices trials.

You should have a resource plan in place to ensure site staff can accommodate an inspection within any given timeframe. Sites will usually be provided with 4 weeks' notice for announced inspections. However, inspections may be unannounced or be performed at short notice.

Inspection scope



Read our annual [GCP Metrics Report\(s\)](#) to see the common compliance issues inspectors have found during GCP inspections.

Inspectors will undertake interviews to help understand processes. However, if there is no supporting documented evidence then this will lead to deficiencies being recorded. You should ensure you have processes in place to allow for the identification, retrieval and management of all documentation on clinical trial related activities.

We will typically review your compliance under five main categories: the protection of participants, protocol compliance, documentation, therapeutic good/investigational product, and trial management (**Table 1**).

We will not review every trial-related document. Inspectors employ a risk-based approach to the type and number of documents we will ask you to provide for an inspection. However, you should maintain inspection readiness across all five categories.

Table 1. Main categories and sub-categories subject to review in a GCP inspection

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

Your inspection responsibilities

Your inspection-related responsibilities include, but are not limited to:

- ensuring your clinical trials are carried out in compliance with Australian regulations and the relevant GCP guideline(s)
- maintaining your readiness for inspection, as inspections may be unannounced
- providing the inspectors, by the given deadline, with any information or documentation they need to prepare or conduct the inspection
- ensuring staff involved in the clinical trial are available (in person or remotely) during the inspection for interview or to clarify issues

- preparation and implementation of appropriate and timely Corrective And Preventative Action (CAPA) plans to address the inspection's findings and prioritise any critical or major deficiencies.

If you have been notified of a GCP inspection, prepare for the inspection by:

- ensuring your authorising institution, trial sponsor and clinical team are advised of the inspection
- ensuring access for the inspectors to clinical trial records and source documents is arranged for the time of the inspection
- ensuring your IT processes allow you to grant view-only access to the inspectors.

We do not impose any obligations on the site to inform the trial sponsor of the inspection. However, there is generally a requirement in the contract between the site and the sponsor to share this type of information. We believe there is benefit in informing the trial sponsor of the inspection.

Common inspection findings: metrics report

To help clinical trial sites prepare for an inspection we publish annual [GCP metrics reports](#) on inspection findings and compliance expectations. Use the metrics report to self-assess if similar compliance issues may need to be addressed at your site.

The information published is de-identified and will not identify individual clinical trial sponsor or investigator or investigator site names. The contents may include, but are not limited to:

- the number of inspections conducted in the previous 12 months and how many were scheduled as routine or 'for cause' inspections
- summary information on critical, major and minor deficiencies and whether they have been resolved.

Our inspection responsibilities

We can request certain information or documents about therapeutic goods exempt under the CTN scheme or approved under the CTA scheme. This can include the investigator's brochure and protocol, further information about safety reports, clarification about the safety profile of a specific therapeutic good, and/or details of problems or complaints.

We can require the trial sponsor of the goods exempt under the CTN scheme, or the person who is granted approval under the CTA scheme, to provide this information or these documents.

We have the authority to inspect clinical trial sites of medicines, biologicals and devices for trials approved under the CTA scheme, and trials of goods exempt under the CTN scheme.

In addition, we may release the inspection report and associated documents prepared by inspectors to approving authorities and responsible ethics committees (see Compliance and Enforcement).

Our inspection-related responsibilities include, but are not limited to:

- coordinating the inspection and personnel—including scheduling dates, times, venues—and providing the agenda
- producing our identity card if requested
- carrying out the inspection
- preparing the inspection report
- reviewing your CAPA plan(s) and finalising the inspection.

Our staff are subject to various confidentiality obligations found in the *Public Service Regulations 1999*, *Public Service Act 1999*, and the *Criminal Code Act 1995*. As such we do not enter into confidentiality deeds in connection with the performance of our statutory functions, including audits and inspections.

If you have been notified of an inspection, we will prepare an inspection plan, which will tell you:

- the objectives and scope of the inspection
- our inspection team member(s) and their role(s)
- the inspection date and site(s) to be inspected
- the specific documents, electronic tools, and systems to be reviewed and which we require access to
- the expected time and duration of each major inspection activity.

We may also request specific electronic documents before the inspection. This is to allow sufficient pre-inspection analysis and inspection planning and will specify a time frame for their delivery. You may provide such documentation to us by means that meet your data privacy processes. Options include a secure email, provision of access to secure file hosting service or provision of electronic media.

Types of inspections

Routine inspections

Routine GCP inspections are scheduled as part of the inspection program. There is no specific trigger for these inspections, although we take a risk-based approach to prioritising them. These inspections are usually of a single investigator site of a specific clinical trial. Please note that other sites may be selected to verify and give practical evidence of compliance.

‘For cause’ inspections

‘For cause’ inspections are undertaken in response to specific triggers where a GCP inspection is the appropriate way to examine the issues. ‘For cause’ inspections generally focus on specific aspects of the clinical trial at a particular investigator site or examine identified compliance issues and their impact. However, we may also inspect other sites because of a trigger. Significant safety concerns or identified noncompliance are expected to be the most common triggers.

Announced and unannounced inspections

We expect most inspections will be announced. That is, we will tell you in advance to ensure the relevant personnel will be available for the inspection. However, it may sometimes be appropriate to conduct unannounced inspections or to perform an inspection at short notice. For example, when an announcement could compromise the objectives of the inspection or when prompt inspection is required because of urgent safety concerns.

Re-inspections

There is no re-inspection planned for clinical trials inspected as part of our routine inspection program. We will prioritise all routine inspections based on risk. However, if a previous inspection of a clinical

trial identified noncompliance this may increase the chance you will be inspected at some time in the future. For example, we may re-inspect:

- where we have identified significant noncompliance
- to evaluate your ongoing compliance with requirements and evaluate changes to your clinical trial management systems.
- to verify you have taken appropriate corrective and preventative action in response to address noncompliance, particularly 'for cause' inspections.

Remote/Hybrid inspections

Sometimes we will perform GCP inspections remotely using video or teleconferencing. For example, where access to the investigator sites or other sites is difficult. If a remote inspection reveals issues that need an on-site inspection, or the inspection objectives could not be met remotely, we may visit the inspection site.

Inspection process

Site selection

Most GCP inspections will be trial-specific, routine inspections of regulated clinical trials. However, other types of inspections including 'for cause' inspections may also occur.

A risk-based approach is undertaken in selecting and prioritising clinical trial sites for GCP inspections. We focus on early phase trials of new medicines, biologicals, [high risk medical devices](#), combinations of medicines, or where there may be safety or other concerns. Trials with higher risk are more likely to be inspected.

Site selection is based on risk assessment proposed by the National Health and Medical Research Council (NHMRC) in [Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods](#).

The risk criteria fall into 2 categories:

- investigational product (medicine, biological, device)
- trial conduct, design, and methods.

In addition, we will consider other elements, including but not limited to the following:

- type of site i.e. located at large institution vs. small clinic
- geographic location i.e. sites are selected from all over Australia including regional and metropolitan areas
- number of participants screened, enrolled, and withdrawn for the trials at the site
- compliance history of the investigator sites and sponsor, including findings from previous GCP inspections of investigator sites.

We will not inspect every CTN or CTA trial. Our GCP inspection procedures have been modelled on those published by the European Medicines Agency (EMA). Most international regulators choose a small percentage, between 1 and 3%, of regulated clinical trials for inspection each year.

Inspection announcement

We will issue the inspection notification announcement to the PI or a representative of the site to be inspected. We will:

- request confirmation of the site PI's availability
- ask for the cooperation of all parties
- confirm in writing that the PI agrees to the inspection of all relevant sites
- ask you to make all required documents and databases directly accessible to our inspectors.

We will normally give you advance notice of our intention to conduct a GCP inspection. However, we have the right to perform a GCP inspection at any time. In exceptional circumstances, we can perform an inspection without notice.

The time between the inspection announcement and the start of the inspection period of notice served should be sufficient for you to make logistic arrangements. You should ensure key personnel are available that have access to relevant data. As a guide, we consider four weeks' notice to be sufficient for a routine inspection.

Notice of the inspection would include:

- the GCP inspector's name(s)
- the inspection's objectives and nature
- the inspection dates
- the address(es) to be inspected.

We may also request information about the clinical trial so we can plan the inspection.

Pre-inspection

We will invite you to attend a remote pre-inspection meeting to introduce the inspection team, including our observer(s) if any.

We may also request trial-related documents including, but not limited to:

- copies of the clinical trial protocol
- investigator's brochure
- monitoring letters
- research governance standard operating procedures (SOPs)
- trial specific user manuals
- statistical analysis plans.

We will give you clear advice on when and how to submit these.

During an inspection

The inspection will proceed according to the details set out in the inspection plan. We will negotiate these details with you before the inspection. They can be amended during the inspection to ensure we achieve the inspection objectives.

Any amendment to the plan will be documented. The inspection will take place over several days, typically 3 consecutive days, depending on the complexity of the trial.

We may collect relevant information to support the inspection and verify compliance with the study protocol, the GCP guideline(s) and the National Statement by, for example:

- interviewing appropriate staff members about trial related activities
- reviewing applicable site policies and procedures regarding research governance activities
- examination or demonstration of computers, electronic systems, and databases, where required, to access clinical trial data
- reviewing adverse event case documentation
- reviewing internal and external communication relevant to HREC or site governance
- reviewing staff training records in relation trial related activities.

Opening meeting

Our inspection team will have an opening meeting with the study site principal investigator, other site staff, and institution and sponsor representatives by invitation before the inspection begins.

The purpose of the opening meeting is to:

- introduce the inspection team
- inform about the regulatory framework for conducting the inspection
- give information about the inspection's scope and objectives
- clarify logistics, timeframes and other matters referred to in the inspection plan
- allow you to introduce your representatives attending the inspection
- allow you to present an overview of the conduct of the trial at your site
- clarify with you whether there are any anticipated difficulties about the conduct of the inspection.

Closing meeting

At the end of the inspection, our inspectors will conduct a closing meeting with the study site principal investigator, members of the study team, and by invitation representatives of the institution and study sponsor. The purpose of the meeting is to:

- summarise the list of observations identified during the inspection to ensure you clearly understand them
- explain the procedures and timelines for distribution of our inspection report, your response, and any follow-up measures
- give you an opportunity to correct any misconceptions and misunderstandings in the observations.

If the inspection is prematurely terminated because of exceptional circumstances, we will document the reason for the early termination and any deviations from the inspection plan in the inspection report.

After an inspection

Inspectors will usually issue the GCP inspection report and cover letter within 30 days of completing the inspection. You will not be issued with a compliance certificate or any form of clearance, registration, or accreditation.

We will keep a record of GCP inspection data, including inspection plans, finalised inspection reports and close-out letters, as well as any evidence of confirmed deficiencies. We handle and store this information in a way that allows it to be accurately reported, interpreted and verified.

Our records management system for documents related to GCP inspection planning and reporting ensures the documents can be retrieved, and that measures taken to investigate deviations from regulatory compliance or GCP concerns can be traced.

Inspection report

If our inspection identifies deficiencies, the outcomes of the inspection may include but are not limited to:

- we may ask you to prepare a Corrective And Preventative Action (CAPA) plan on the template provided with the inspection report;
- enforcement action may be taken under the Therapeutic Goods legislation if required. This may include action to stop your trial.

If you are asked to prepare a CAPA plan, you should provide this to the inspectors within the agreed timeline, usually within 30 days of receiving the inspection report. When you submit the CAPA plan, you may also comment on any major factual errors in the inspection report, if any. If we do not receive your response within the agreed time, this will be recorded in the inspection related documentation.

You can request a meeting with the inspectors to discuss your CAPA plan. We will review the CAPA Plan and may request additional objective evidence to verify the completion of corrective actions for some deficiencies. We will assess the impact of any comments on the inspection findings and the appropriateness of the proposed CAPA and proposed time frames.

We will document our assessment of the CAPA plan. If we do not accept your proposed CAPA or timeframes for actions, additional follow-up will occur to reach an agreement.

We will close the inspection when we have agreed on an acceptable CAPA plan. The lead inspector will sign the final inspection report and associated close-out letter and issue these to you.

Our inspectors may ask you for ongoing evidence of completion or updates on your CAPA activities. This evidence is required to be filed at your site. This evidence may be reviewed by the inspectors during another inspection at your site, if applicable.

Grading of inspection findings

Deficiencies are classified by the assessed risk level and may vary depending on the nature of the investigational product.

Deficiencies found during the inspections are graded at three levels (critical, major, minor). A deficiency recorded for one of the five main categories may be comprised of a number of minor, major and critical findings.

The grading recorded for the main category deficiency is set to the highest-level finding.

The inspection report may include comments on observations. These comments might lead to suggestions on how to improve quality or reduce the potential for a deviation to occur in the future.

Critical deficiency

A 'critical deficiency' is an issue in clinical trial systems, practices or processes that:

- adversely affects the rights, safety or well-being of clinical trial participants; or
- adversely affects the quality or integrity of data; or
- represents a serious violation of applicable legislation and guidelines.

Deficiencies classified as critical may include a pattern of deviations classified as major.

A critical deficiency also occurs when a party is observed to have engaged in fraud, misrepresentation, or falsification of data.

In some circumstances an otherwise major deficiency may be categorised as critical. For example, a deficiency reported after a previous inspection and not corrected may be given higher classification.

Major deficiency

A 'major deficiency' is an issue in clinical trial systems, practices or processes that:

- could adversely affect the rights, safety or well-being of clinical trial participants,
- could adversely affects the quality or integrity of data; or
- represents a violation of applicable legislation and guidelines.

Deficiencies classified as major may include a pattern of deviations classified as minor.

Minor deficiency

A 'minor deficiency' is an issue in clinical trial systems, practices or processes that would **not** be expected to adversely affect the:

- rights, safety or well-being of clinical trial participants; or
- quality or integrity of data.

Compliance and enforcement

The [Regulatory Compliance Framework](#) sets out our overall approach to compliance. If an inspection leads to regulatory actions being taken under the Act, this information will be published in line with our compliance and enforcement procedures. Such publications can include identification of the parties and offences for more serious contraventions of the Act and/or Regulations.

Where the GCP inspection process identifies deficiencies, we will work with you to address the deficiencies. For example, by providing you with guidance and examples of best practice where available. If necessary, we may take enforcement action, which could include action to stop your trial.

Inspection findings, including the inspection reports and other associated documents, can be released to the approving authority and/or approving HREC under the [Therapeutic Goods \(Clinical Trial Inspections\) Specification 2020 \(No.2\)](#) ("the Specification"). This information does not include any personal or sensitive information in relation to participants of the clinical trial.

If you refuse us access to any relevant record or documentation that our inspectors have a legal right to access, this will be documented in the inspection report so we can determine further action and consequences.

Contacts

For any GCP-related enquiries, please email GCP.Inspection@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original guidance	Pharmacovigilance Branch, Therapeutic Goods Administration	April 2022
V2.0	Incorporation of medical devices into the GCP inspection program Minor updates and clarifications for currency Restructure to improve readability Deletion of material on legal framework and responsibilities which are covered in the Australian Clinical Trials Handbook	Pharmacovigilance Branch, Therapeutic Goods Administration	May 2024

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