Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Good Clinical Practice (GCP) Inspection Program 2025

A report on Therapeutic Goods Administration (TGA) clinical trial compliance activities

Version 1.0, May 2026

Copyright

Contents

Purpose 4

Background 4

Stakeholder engagement and education 5

Overview of conducted inspections 6

Summary of inspection outcomes 8

Overview of deficiencies by sub-category and examples of major deficiencies 9

- Main Category: Protection of participants 9
- Main Category: Protocol compliance 10
- Main Category: Documentation 11
- Main Category: Therapeutic good (TG) / Investigational product (IP) 14
- Main Category: Trial management 15

Comparison of GCPIP inspection outcomes over time 17

Appendix A: Inspection deficiency gradings 18

Appendix B: ALCOA-C data integrity principles 19

Appendix C: Definition of unapproved TGs 20

Purpose

This report summarises the outcomes of inspections conducted by the Good Clinical Practice Inspection Program (GCPIP) from **1 January 2025** to **31 December 2025**, including:

- areas of compliance and non-compliance with the GCP standards, the applicable Australian therapeutic goods legislation and other relevant guidelines
- examples of major deficiencies identified in GCP inspections
- an overview of education activities undertaken by the GCPIP.

It aims to support:

- GCP inspection readiness
- clinical trial sites to meet the therapeutic goods legislation and GCP guideline(s) requirements
- high quality clinical trials in Australia.

This report should be read in conjunction with:

- GCP Inspection Guidance
- Australian Clinical Trial Handbook
- Roles and responsibilities for clinical trial safety reporting of significant safety issues and urgent safety measures

Background

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

We inspect Australian clinical trial sites involved in clinical trials of medicines, biologicals and medical devices conducted under the Clinical Trial Notification (CTN) and Clinical Trial Approval (CTA) schemes. The GCPIP commenced inspecting trials of medicines and biologicals in August 2022 with medical device trials added to the program in November 2023. During inspections, we assess whether sites are meeting their GCP responsibilities and their compliance with the applicable Australian therapeutic goods legislation and guidelines.

Further details on the type of inspections, who we inspect, how we prioritise and schedule inspections, and the overall inspection process is available in our GCP Inspection Guidance document. This document also includes definitions for terms frequently used in this report.

Previous versions of the TGA GCPIP metrics report are available on our webpage

In this report

- we refer to the TGA as 'we' or 'our'
- we use the following terms interchangeably:
  - 'clinical investigation' and 'clinical trial'
  - 'protocol' and 'clinical investigation plan (CIP)'.

Stakeholder engagement and education

Our education initiatives aim to inform and engage with stakeholders and provide up-to-date, clear, and accessible guidance and information to assist regulated entities with compliance.

The educational outreach activities delivered in 2025 included:

- direct education to 21 clinical trial sites before, during and after inspections to promote compliance and understanding of the relevant Australian legislation and guidelines
- public consultation on ICH GCP E6(R3) to inform adoption and support alignment with international standards in accordance with Australian regulatory requirements
- publication of the 2023–2024 metrics report supported by a live public webinar and Q&A opportunities
- redesign of the GCPIP webpages to improve findability on the TGA website and in search engines, and support easy digital scanning with a clear structure and prominent information up front.

We participated in 8 conferences and external events. Topics covered included the GCPIP, TGA compliance expectations and broader TGA clinical trials reforms.

Overview of conducted inspections

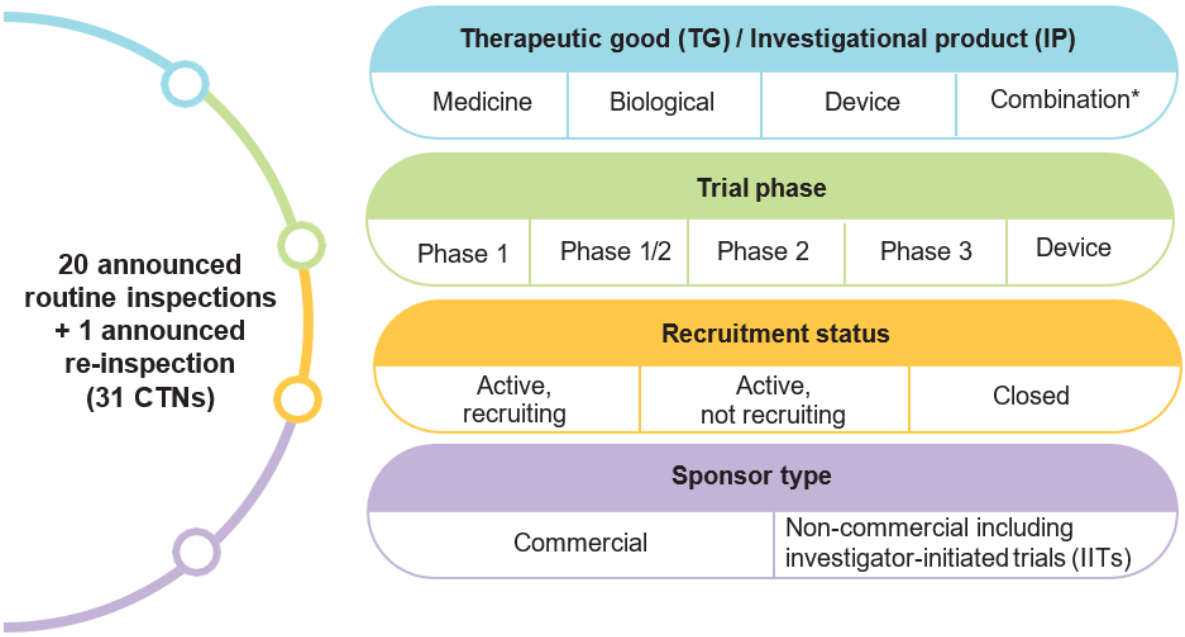
This report covers the period of **1 January 2025** to **31 December 2025**.

While this report focuses on areas for improvement identified through the inspections conducted in the reporting period, the inspection program found a strong commitment to compliance with GCP, reinforcing confidence in the quality of Australian clinical trials. At the time of publication of this report, all sites had resolved the identified issues through a corrective and preventative action (CAPA) process.

All data in this report has been **de-identified** and does not reveal the identities of individual clinical trial sites, investigators, sponsors, Human Research Ethics Committees (HRECs), local approving authorities (AAs) or any other relevant stakeholders. Refer to the TGA Privacy webpage to learn about how we handle personal information.

A total of 21 inspections were conducted in this reporting period. These comprised of 20 announced routine GCP inspections and one announced re-inspection. Thirty-one CTNs were included in these inspections and six inspections included 2 or more CTNs. No CTAs were inspected during this period. Most inspections were conducted in-person over 1-2 days and included private and public sites. Figures 1-3 provide further information, by CTN, on the clinical trial sites and trials we inspected.

Figure 1: TGA GCP inspections conducted in 2025



* Combination included a medicine and/or biological and/or device
Figure is not intended to convey the proportion of each trial attribute included in the 21 inspections.

Figure 2: TGA GCP inspections conducted in 2025 by state/territory

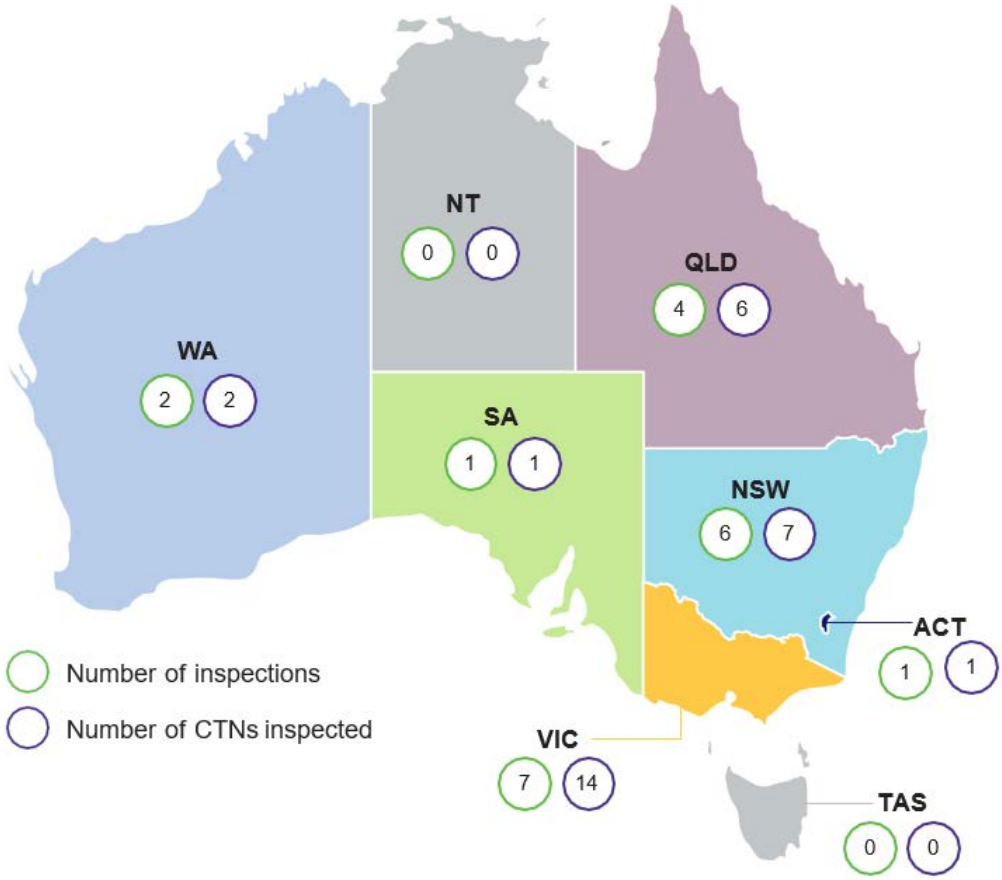
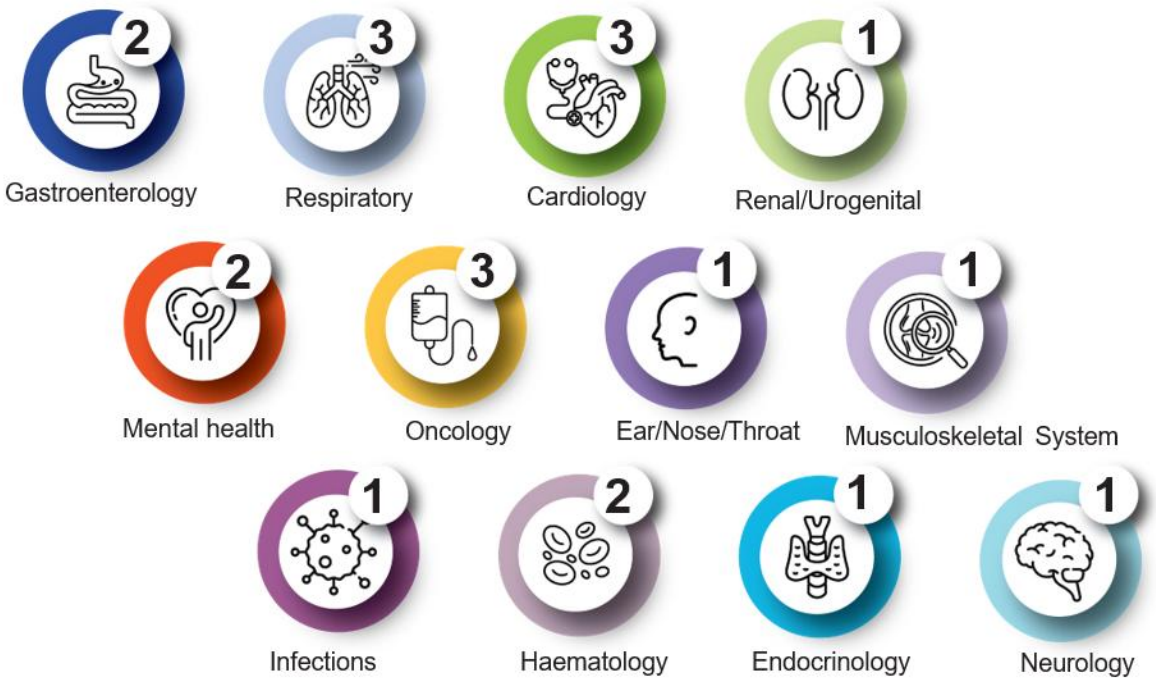


Figure 3: Inspections conducted in 2025 by therapeutic area



Summary of inspection outcomes

Deficiencies identified during GCP inspections are graded as either minor, major or critical (see Appendix A for definitions of inspection gradings).

Compliance is reviewed under 5 main categories:

- Protection of participants
- Protocol compliance
- Documentation
- Therapeutic good / Investigational product
- Trial management

There are 28 sub-categories within these 5 main categories which are outlined in the GCPIP Guidance document.

An inspection may reveal minor, major and critical deficiencies across sub-categories within a main category, but only one overall deficiency is reported per main category. The main category's grade reflects the highest-level deficiency or deficiencies found in its sub-categories.

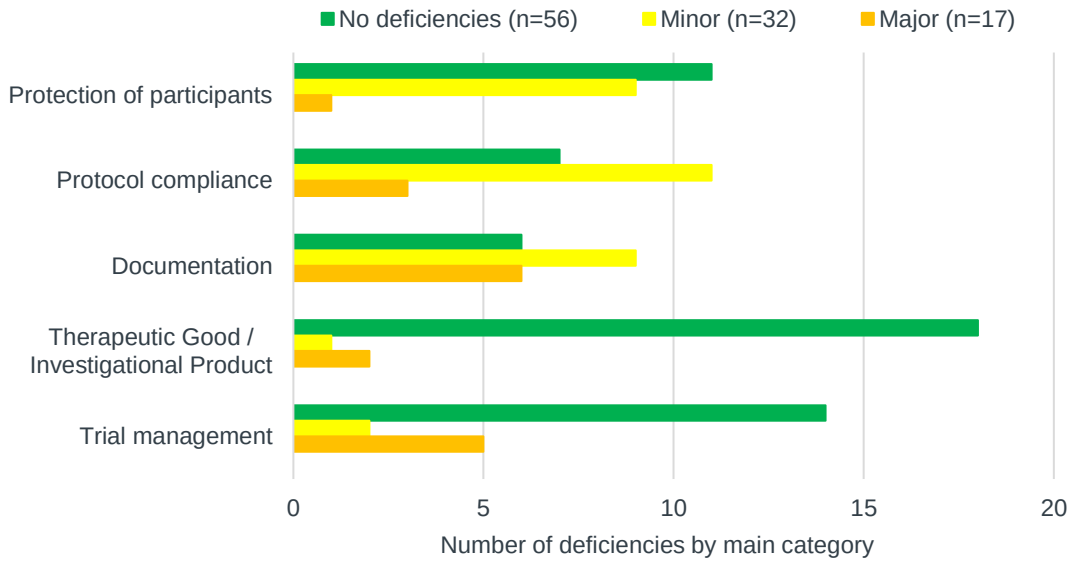
Overall, inspection outcomes demonstrated a high level of compliance:

- 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 and the highest level of non-compliance was observed in the ‘Documentation’ category (Figure 4).

At least one major deficiency was reported in each main category. Examples of these and their distribution across the 28 sub-categories, is discussed in the next section of this report.

Figure 4: Summary of main category deficiencies in 2025 inspections



Overview of deficiencies by sub-category and examples of major deficiencies

For each of the 5 main categories, the distribution of deficiencies identified across all associated sub-categories are presented below. De-identified examples of major deficiencies from inspections conducted in 2025 are also discussed.

Main Category: Protection of participants

Ten inspections included a deficiency in the main category of 'Protection of participants'. Of these inspections, one deficiency was graded major and 9 deficiencies were graded as minor.

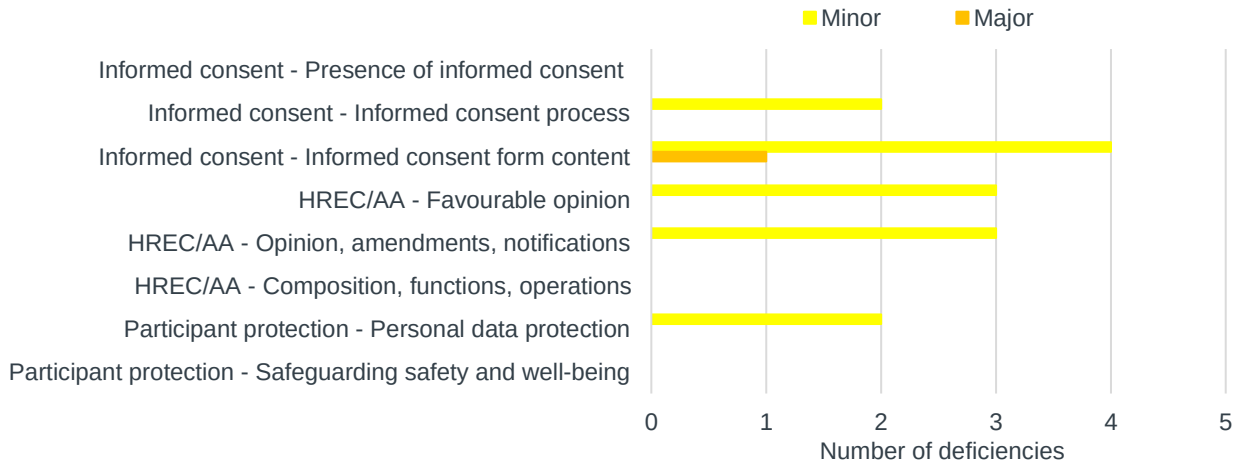
The main category of 'Protection of participants' is comprised of 8 sub-categories. Overall, 15 sub-category deficiencies were identified, as presented in Figure 5 below.

No deficiencies were identified in any inspection for 3 sub-categories:

- Informed consent – Presence of informed consent
- HREC/ AA – Composition, functions, operations
- Participant protection – Safeguarding safety and well-being.

The sub-category 'Informed consent – Informed consent form content' had the most deficiencies attributed to it (5), including the only major deficiency for the main category of 'Protection of participants.' The major deficiency is discussed below.

Figure 5: All deficiencies in the Protection of participants category



Example of a major deficiency in the Protection of participants category

ICH GCP E6(R2) section 4.8.10 requirements that 'the informed consent discussion and the written informed consent and any other written information to be provided to participants should include specific explanations' were not always met because required sections were missing without justification. For example, there was no statement/information regarding:

- 'The compensation and/or treatment available to the participant in the event of trial- related injury' (ICH GCP E6(R2) section 4.8.10 (j)).
- 'That the monitor(s), the auditor(s), the HREC, and the regulatory authority(ies) will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorising such access' (ICH GCP E6(R2) section 4.8.10 (n)).
- 'That the participant or the participant's legally acceptable representative will be informed in a timely manner if information becomes available that may be relevant to the participant's willingness to continue participation in the trial' (ICH GCP E6(R2) section 4.8.10 (p)).
- 'The foreseeable circumstances and/or reasons under which the participant's participation in the trial may be terminated' (ICH GCP E6(R2) section 4.8.10 (r)).

Main Category: Protocol compliance

Fourteen inspections included a deficiency in the main category of 'Protocol compliance'. Of these inspections, 3 deficiencies were graded major and 11 deficiencies were graded as minor.

The main category of 'Protocol compliance' is comprised of 6 sub-categories. Overall, 18 sub-category deficiencies were identified, including 4 major and 14 minor deficiencies, as presented in Figure 6 below.

No deficiencies were identified in any inspection for 2 sub-categories:

- Assessment of efficacy
- Non-compliance with safety reporting to HREC/AA/TGA.

The sub-category 'Other protocol non-compliance not listed above' had the most deficiencies attributed to it (11), including 2 major and 9 minor deficiencies. Two major deficiencies, and one minor deficiency, were also identified in the sub-category 'Eligibility criteria'.

Figure 6: Individual deficiencies in the Protocol compliance category

Example of major deficiencies in the Protocol compliance category

ICH GCP E6(R2) section 4.5.2 requirements that 'the investigator should not implement any deviation from the protocol any deviation from, or changes of the protocol without prior review and documented approval/favourable opinion from the HREC' were not always met. Incidents were observed where deviations were implemented without agreement from the reviewing HREC. For example,

- enrolment of an ineligible participant who subsequently received the intervention
- assessment of a participant against an exclusion criterion via methods not described in the protocol.

ICH GCP E6(R2) section 4.5.3 requirements that 'the investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol' were not always met as deviations were either not documented and/or explained. For example,

- protocol required assessments were not completed
- information supplied to participants relating to the IP differed to the instructions provided in the protocol
- a delay in reporting a Serious Adverse Event to the sponsor was not documented and explained.

Main Category: Documentation

Fifteen inspections included a deficiency in the main category of 'Documentation'. Of these inspections, 6 deficiencies were graded major and 9 deficiencies were graded as minor.

The main category of 'Documentation' is comprised of 9 sub-categories. Overall, 28 sub-category deficiencies were identified, including 9 major and 19 minor deficiencies, as presented in Figure 7 below.

No deficiencies were identified in any inspection for 4 sub-categories:

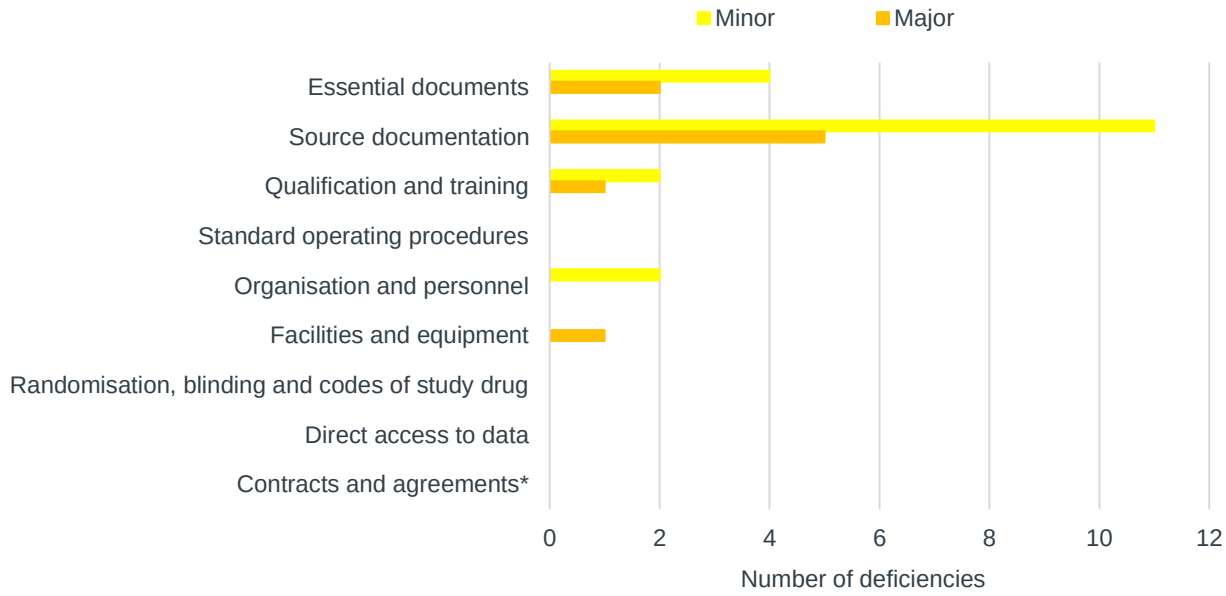
- Standard operating procedures
- Randomisation, blinding and codes of study drug

- Direct access to data
- Contracts and agreements, including PI oversight of contractors/site-hired third-party vendors.

The sub-category ‘Source documentation’ had the most deficiencies attributed to it (n=16), including 5 major and 11 minor deficiencies. This was followed by the sub-category ‘Essential documents’ (n=6) with 2 major and 4 minor deficiencies.

Most deficiencies in ‘Documentation’ were due to non-compliance with the ALCOA-C principles (see Appendix B for an explanation of the ALCOA-C principles).

Figure 7: Individual deficiencies in the Documentation category



* Contracts and agreements, including PI oversight of contractors/site-hired third-party vendors

Example of major deficiencies in the Documentation category

Multiple sections in GCP require clinical trial information to be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification. Examples of non-compliance included:

- ICH GCP E6(R2) section 4.9.0 requirements that 'the investigator should maintain adequate and accurate source documents and trial records that include all pertinent observations on each of the site's trial participants' and that 'source data should be ALCOA-C' were not always met.
- ICH GCP E6(R2) section 4.9.4 requirements that 'the investigator should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.)' were not always met.
- ICH GCP E6(R2) section 4.9.2 requirements - that 'data reported on the CRF, that are derived from source documents, should be consistent with the source documents or the discrepancies should be explained' were not always met.
- ISO14155:2020 section 7.8.1 requirements that 'all documents and data shall be produced and maintained in a way that ensures reliability, integrity, control and traceability' were not always met.
- ICH GCP E6(R2) section 4.1.5 requirements that 'the investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties' was not always done.
- ICH GCP E6(R2) section 4.2.3 requirements that the investigator should have available 'adequate facilities for the foreseen duration of the trial to conduct the trial properly and safely' was not always met as there were no records of the maintenance, calibration or servicing of any equipment used in the inspected trial available.

Main Category: Therapeutic good (TG) / Investigational product (IP)

A definition of 'unapproved therapeutic goods' is provided in Appendix C.

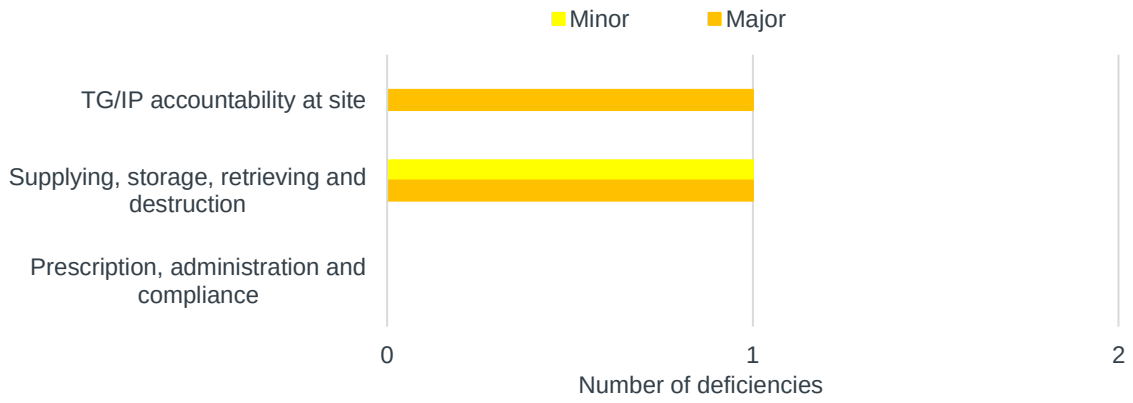
Three inspections included a deficiency in the main category of 'TG/IP'. Of these inspections, 2 deficiencies were graded major and one deficiency was graded as minor.

The main category of 'Protocol compliance' is comprised of 3 sub-categories. Overall, 3 sub-category deficiencies were identified, including 2 major and one minor deficiency, as presented in Figure 8 below.

No deficiencies were identified in any inspection for the sub-category 'Prescription, administration and compliance'.

The sub-category 'Supplying, storage, retrieving and destruction' had the most deficiencies attributed to it (2), with one major and one minor deficiency. The sub-category 'TG/IP accountability at site' had one major deficiency.

Figure 8: Number of individual deficiencies in the TG / IP category



Example of major deficiencies in the TG / IP category

ICH GCP E6(R2) section 4.6.3 requirements that the investigator or other appropriate individual, who is designated by the investigator, to maintain records of the use by each participant, the return or alternative disposition of unused product(s), and to reconcile the IP was not always met. For example,

- the dose and time of IP self-administration was not documented
- the disposition of returned IP was not documented
- there was no record of IP reconciliation.

ICH GCP E6(R2) sections 5.13.1 and 5.13.2 requirements that the sponsor ensures the IP is manufactured, labelled, packaged and stored in accordance with applicable Good Manufacturing Practice (GMP) were not always met. For example, there was no documentation to justify the assigned expiry date and storage conditions of the manufactured IP.

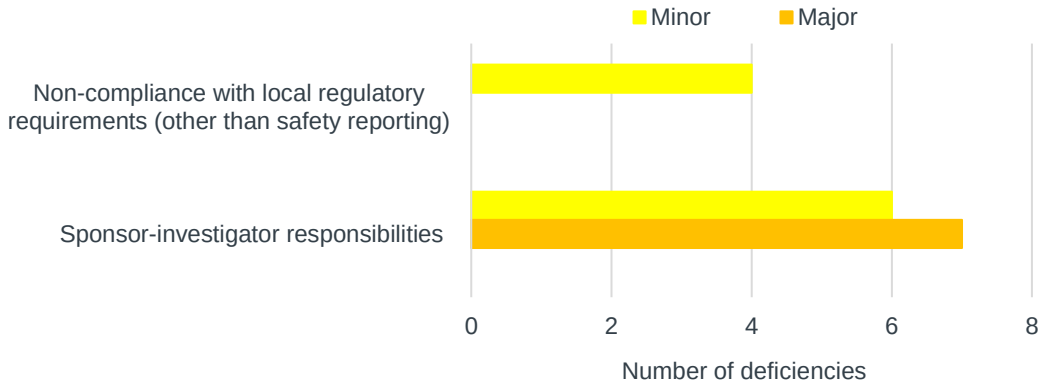
Main Category: Trial management

Seven inspections included a deficiency in the main category of 'Trial management'. Of these inspections, 5 deficiencies were graded major and 2 deficiencies were graded as minor.

The main category of 'Trial management' is comprised of 2 sub-categories. Overall, 17 sub-category deficiencies, including 7 major and 10 minor deficiencies, as presented in Figure 9 below.

The sub-category 'Sponsor-investigator responsibilities' applicable to IITs had the most deficiencies attributed to it (13), including 7 major and 6 minor deficiencies. A minor and/or major deficiency in this sub-category was identified in all inspected IITs. The sub-category 'Non-compliance with local regulatory requirements (other than safety reporting)' had 4 minor deficiencies.

Figure 9: Individual deficiencies in the trial management category



Example of major deficiencies in the Trial management category

Multiple sections in GCP cover sponsor-investigator responsibilities. Examples of non-compliance included:

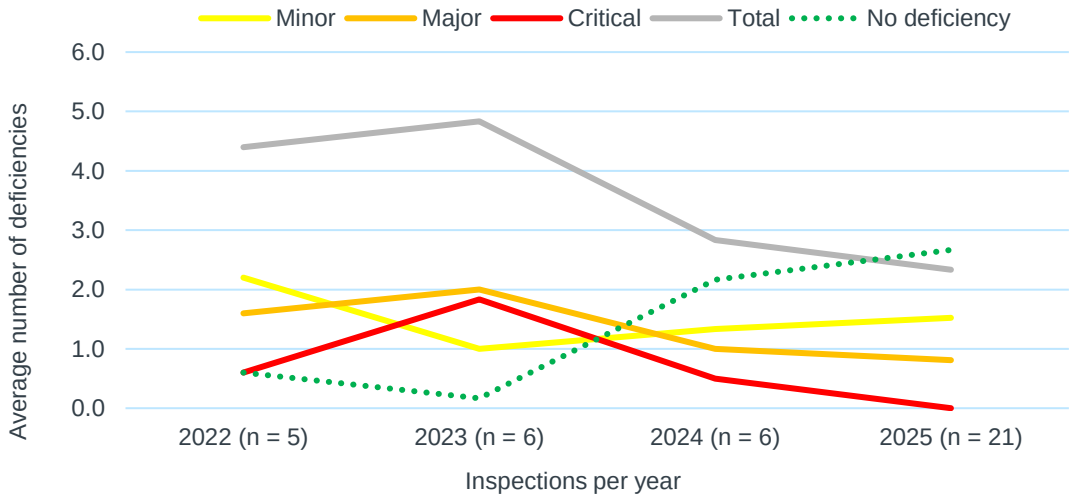
- ICH GCP E6(R2) section 5.0 requirements (and consequently section 5.1.1) that the sponsor-investigator should implement a system to manage quality throughout all stages of the trial process were not always met. For example, there were no quality management systems in place to
  - ensure that protocols, case report forms, and other operational documents were clear, concise, and consistent (ICH GCP E6(R2) section 5.0)
  - identify processes and data critical to ensure participant protection and reliability of trial results (ICH GCP E6(R2) section 5.0.1)
  - identify, evaluate, control, document, review and report any risks to critical trial processes and data (ICH GCP E6(R2) section 5.0.2 – 5.0.7).
- ICH GCP E6(R2) section 5.18 requirements that the sponsor-investigator should develop a systematic, prioritised, risk-based approach to monitoring clinical trials were not met because the sponsor-investigator did not:
  - appoint a monitor (ICH GCP E6(R2) section 5.18.2)
  - determine the extent and nature of monitoring (ICH GCP E6(R2) section 5.18.3)
  - undertake any monitoring of the IP (ICH GCP E6(R2) section 5.18.4 (c))
  - have an established SOP or process for monitoring the trials (ICH GCP E6(R2) section 5.18.5)
  - have a monitoring plan (ICH GCP E6(R2) section 5.18.7).
- ICH GCP E6(R2) section 6 requirements for protocol contents were not always met because several sections of the protocol were missing without justification. Examples of unjustified omissions include:
  - A statement that the trial will be conducted in compliance with the protocol, GCP and the applicable regulatory requirement(s) (ICH GCP E6(R2) section 6.2.5)
  - The identification of any data to be recorded directly on the CRFs (i.e., no prior written or electronic record of data), and to be considered to be source data (ICH GCP E6(R2) section 6.4.9)
  - The type and duration of the follow-up of subjects after adverse events (ICH GCP E6(R2) section 6.8.4).

Comparison of GCPIP inspection outcomes over time

Analysis of outcomes from the inspection program over the first 4 years shows:

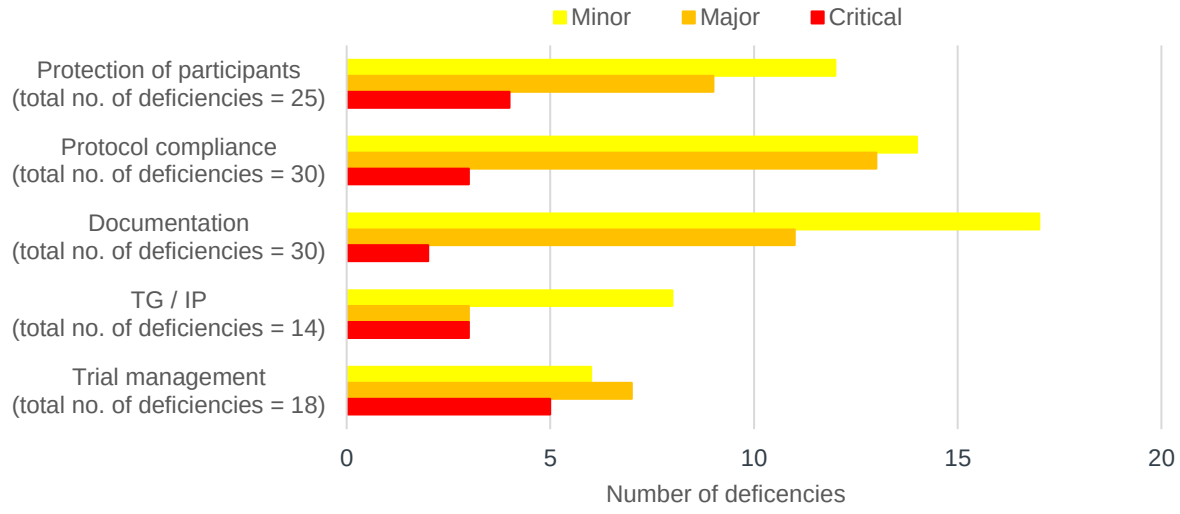
- the number of inspections conducted increased in 2025
- the average number of deficiencies per inspection has decreased (Figure 10)
- on average, the number of inspections with no deficiencies has increased (Figure 10)
- over time, both the frequency and severity of identified deficiencies has declined.

Figure 10: Average number of deficiencies per inspection over time



The total number and grading of deficiencies by main categories since the commencement of the GCPIP is presented in Figure 11. Compared with the current 2025 reporting period, the main categories of ‘Protocol compliance’ and ‘Documentation’ continue to be the categories with the highest number of identified deficiencies, irrespective of grading.

Figure 11: Total number and grading of deficiencies by main category since the commencement of the GCPIP



Appendix A: Inspection deficiency gradings

Excerpt from the GCP Inspection Guidance document

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.*

Appendix B: ALCOA-C data integrity principles

Documentation should meet the ALCOA-C principles to ensure data integrity at a clinical trial site:

Attributable	Is it obvious who wrote/did it/made a change and when?
Legible	Can the data be read easily?
Contemporaneous	Are the data recorded in real time? Are signatures dated?
Original	Is it a primary source? Is the original available? Is the original protected against premature destruction?
Accurate	Is the information error free? Is there a quality control/assurance process? Are conflicting data recorded elsewhere?
Complete	Has the information been recorded in its entirety?

Appendix C: Definition of unapproved TGs

What are 'therapeutic goods'?
'Therapeutic goods' are defined in Section 3 of the *Therapeutic Goods Act 1989*.

Australian Register of Therapeutic Goods (ARTG) is the public database of therapeutic goods approved for supply in Australia.

Unapproved therapeutic goods are:

- not included in the ARTG
- included in the ARTG but used in a manner not covered by the existing entry in the ARTG. This includes:
  - **Medicines**
    - any new formulation, strength or size, dosage form, name, indications, direction for use, type of container.
  - **Medical devices** (including an *in vitro* diagnostic device (IVD)):
    - any new manufacturer, device nomenclature system code, classification or unique product identifier (for certain classes of medical devices only)
    - any in-house IVD where the laboratory providing the in-house IVD is unable to comply with the regulatory requirements for in-house IVDs.
  - **Biologicals**
    - Class 1 or 2 biological, any new applicable standards, intended clinical use, principal manufacturer.
    - Class 3 or 4 biological, any new product name, dosage form, formulation or composition, therapeutic indication, type of container, principal manufacturer.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Pharmacovigilance Compliance and Clinical Trials Section	May 2026

OFFICIAL

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 1800 020 653 Fax: 02 6203 1605
Web: tga.gov.au

Reference: D25-4365437