

Applying GCP to Audits of Clinical Trials

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NSW Regional Health Partners

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Working together for good health and wellbeing

Clinical Trials and Data Platform

Sydney HealthPartners

This presentation covers

- Objectives of a clinical trial
- Good Clinical Practice (GCP) and its application to clinical trials
- GCP clinical trial auditing

Glossary

Curriculum Vitae (CV)

Food and Drug Administration (FDA)

Good Clinical Practice (GCP)

International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Institutional Review Board (IRB). The term Human Research Ethics Committee (HREC) is used in Australia

Therapeutic Goods Administration (TGA)



Image: Diane Serik from Unsplash

Part 1

Objectives of a clinical trial

Good Clinical Practice (GCP) and its application to clinical trials

GCP clinical trial auditing

Objectives of a clinical trial

Clinical trials are essential to the development of new interventions

- Ensure new interventions are safe and effective
- Advance medical knowledge
- Improve patient care and quality of life

https://www.australianclinicaltrials.gov.au/about/what-is-a-clinical-trial

What is a clinical trial?

"A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes."

World Health Organisation (WHO) – What is a clinical trial 2020



Image: Lucas Vasques from Unsplash

Guidance and Regulatory Framework References

- TGA Note for ICH Guideline for GCP
- TGA GCP Inspection Program
- NHMRC National Statement Ethical Conduct Human Research 2025
- Australian Code for the Responsible Conduct of Research
- TGA Australian Clinical Trial Handbook
- National Clinical Trials Governance Framework
- National Standard Operating Procedures For Clinical Trials in Australia
- Declaration of Helsinki



Images: Sourced from webpages on left

Part 2

Objectives of a clinical trial

Good Clinical Practice (GCP) and its application to clinical trials

GCP clinical trial auditing

What is GCP?

“Good clinical practice (GCP) is a standard for the planning, initiating, performing, recording, oversight, evaluation, analysis and reporting of clinical trials that provides assurance that the data and reported results are reliable and that the rights, safety and well-being of trial participants are protected.”

[ICH GCP E6 (R3) Glossary]



Who must be trained in GCP?

Compliance with the Good Clinical Practice standards is obligatory for trials involving the investigation of medicinal products for many countries, including Australia.

Training in GCP, and evidence of having successfully completed that training, is mandatory for all clinical trials site personnel.

[The importance of Good Clinical Practice guidelines and its role in clinical trials (nih.gov)]



Image: Drazen Zigic iStock

GCP and clinical trials

The catalyst for GCP was historical experimentation on humans.

International response - compliance with GCP and regulatory guidelines to provide **public assurance that the rights, safety and wellbeing of participants are respected and protected**, and that the data generated are credible and accurate.

The International Council for Harmonisation (ICH) created the set of GCP standards that are used internationally.



Image: https://ich.org/

ICH GCP in Australia

“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.”

Introductory comments of the TGA

Principles of ICH GCP

The ICH E6 (R3) Guidelines were released in January 2025 and are expected to be adopted in Australia with TGA annotations in 2026.

There are 42 principles of GCP, which have been organised into 11 categories, as detailed in the following slides.



11 Categories of ICH-GCP

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with GCP and applicable regulatory requirement(s). Clinical trials should be designed and conducted in ways that ensure the rights, safety and well-being of participants.

2. Informed consent is an integral feature of the ethical conduct of a trial. Clinical trial participation should be voluntary and based on a consent process that ensures participants (or their legally acceptable representatives, where applicable) are well-informed.

3. Clinical trials should be subject to an independent review by an IRB/IEC (Ethics Committee)

11 Categories of ICH-GCP

4. Clinical trials should be scientifically sound for their intended purpose and based on adequate and current scientific knowledge and approaches

5. Clinical trials should be designed and conducted by qualified individuals

6. Quality should be built into the scientific and operational design and conduct of clinical trials

7. Clinical trial processes, measures and approaches should be implemented in a way that is proportionate to the risks to participants and to the importance of the data collected

11 Categories of ICH-GCP

8. Clinical trials should be described in a clear, concise, scientifically sound and operationally feasible protocol

9. Clinical trials should generate reliable results

10. Roles and responsibilities in clinical trials should be clear and documented appropriately

11. Investigational products used in a clinical trial should be manufactured in accordance with applicable Good Manufacturing Practice (GMP) standards and be stored, shipped, handled and disposed of in accordance with the product specifications and the trial protocol

Part 3

Objectives of a clinical trial

Good Clinical Practice (GCP) and its application to clinical trials

GCP clinical trial auditing

What is a clinical trial audit?

"An Audit is a systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's SOPs, GCP, and the applicable regulatory requirements."

Brenda Wright, Chapter 17 - Audits and Inspections, A Comprehensive and Practical Guide to Clinical Trials, Academic Press, 2017



Image: National Cancer Institute from Unsplash

What an auditor reviews at site

The Principal Investigator has overall responsibility for all aspects of trial conduct.

The auditor may review Personnel CVs which should contain:

- Qualifications
- Clinical research experience
- Current position at site
- Signature and date
- Evidence of current GCP training and certification



What an auditor reviews at site

- Signed and dated Confidentiality Agreement
- Signed and dated Investigator Contracts
- Signed and dated Sponsor Agreement
- Signed and dated Clinical Research Organisation Agreement
- Signed and dated Indemnity Agreement
- Signed and dated Financial Agreement
- Signed and dated Protocol Agreement
- Signed Confirmation of Case Report Form data
- Signed US Food and Drug Administration 1572 Forms (if applicable)
- Completed, dated and signed delegating authority logs

What an auditor reviews at site

- HREC approval letters
- HREC correspondence i.e., annual reports
- Informed consent completeness
- CRFs are completed and accurate
- Current versions of protocol, Investigator brochure, PICF
- Approved versions of advertising
- Source data
- Documents signed as required i.e., pathology results
- Participant follow-up and outcome for safety reporting
- Storage of study drug, temperature logs, monitor review, returns
- Review of randomisation codes.

What an auditor reviews at site

- Review of Quality Assurance systems used at site and levels of access
- Documentation for audit trails
- Review of Quality Control applied at every stage of data handling
- Review outcomes other internal/external audits
- Process for Quality Assurance during the trial
- Standard Operating Procedures
- Trial Master File (either electronic or hard copy)

* *Audits can also be undertaken remotely*



Common audit findings

- Patient or investigator signature on Consent Form is not dated
- No version/date on consent form
- Staff CVs not on file
- Ethics Committee members composition list not current
- Ethics Committee letter did not list all documents reviewed
- Ethics Committee letter did not contain statement of GCP compliance
- Drug not temperature monitored (if required)
- Signatures not dated
- Investigator failed to report SAEs

TGA GCP Inspection Program Metrics Reports

Additional references

- VCCC Alliance: Roles involved in conducting clinical trials
- VCCC Alliance: Principal Investigator
- A-CTEC Internal Audit Toolkit (login required – free to join)
- Guidance for best practices for clinical trials

Other audit resources

Please see the other audit resources available on your partner organisation's website:

NSW Regional Health Partners (NSWRHP)

Sydney Health Partners (SHP)

Maridulu Budyari Gumal, the Sydney Partnership for Health, Education, Research and Enterprise (SPHERE)

