Good Clinical Practice (GCP) Basic Course for Support Staff

To register CLICK HERE

Course Overview

Grounded in the South African Good Clinical Practice (SA GCP) 2020 Guidelines, the *GCP Basic for Support Staff Course* introduces non-clinical staff to the ethical and scientific standards that underpin the conduct of clinical trials involving human participants.

The course also provides an overview of key ethical frameworks that guide health research in South Africa and globally:

- The International Council for Harmonisation (ICH) E6(R3) Guideline for Good Clinical Practice, which outlines international standards for designing, conducting, recording, and reporting clinical trials.
- Ethics in Health Research: Principles, Processes and Structures (2024, Version 3.1), South Africa's national guideline governing ethical conduct in health research.

Certification

- Delegates are required to complete a final assessment with at least 70% accuracy.
- Upon successful completion of the course, the delegate will be given access to the GCP for Support Staff Certificate of Completion, valid for 3 years.

CPD Points

- CPD points will be issued with the certificate of completion.

Target Audience

The target audience includes non-clinical support staff involved in the day-to-day operations of clinical research sites, such as counsellors, fieldworkers, recruiters, data capturers, study administrators, and drivers.

It is also suitable for individuals working in administrative or logistical roles who support clinical trial activities and wish to gain a foundational understanding of Good Clinical Practice.

Duration

The classroom training is one and a half (1.5) days (Day 1: from 08h30 to 16h00 and Day 2: 08h30 to 13h00).

Cost

Classroom

WHC	R2,850.00	No Vat
Wits	R3,277.50	Vat Incl
Private	R3,800.75	Vat Incl

Virtual (By prior arrangement)

WHC	R2,460.00	No Vat
Wits	R2,829.00	Vat Incl
Private	R3,300.50	Vat Incl

In-house training will be considered, subject to viability.

training@academicadvance.co.za
+27 11 274 9431/9317/9221
31 Princess of Wales Terrace, Parktown, 2193
https://www.academicadvance.co.za
academic advance
Wits Health Consortium (Pty) Ltd

Learning Outcomes

Module 1: Introduction to Clinical Trials

- Understand what clinical research is and how data is collected (medical records, surveys, interviews, experiments).
- Learn the phases of clinical trials and their purposes.
- Recognise who can participate in clinical trials and the criteria for eligibility.
- Appreciate the importance and process of clinical trials, including participant visits and the role of the research team.

Module 2: Role–players in Clinical Trials

- Identify key role–players: sponsor, regulatory authority, Research Ethics Committees (RECs), investigator, participants, and monitor.
- Understand the responsibilities of each role, including legal, ethical, and operational aspects.
- Learn about the regulatory framework and the function of agencies like SAHPRA and NHRC.

Module 3: Introduction to GCP

- Define Good Clinical Practice (GCP) and its goals: protecting participants, ensuring data quality, and providing standards for research conduct.
- Explore the origins and principles of GCP (ICH E6(R2) vs ICH E6(R3).
- Understand the consequences of not following GCP.

Module 4: SA GCP

- Learn why country–specific GCP guidelines exist and their precedence over international guidelines in South Africa.
- Review the SA GCP framework, including chapters on key concepts, recruitment, regulatory roles, investigator and sponsor responsibilities, protocol, essential documents, and other considerations.

Module 5: Ethics

- Understand the definition and importance of ethics in research.
- Learn about the regulation of health research in South Africa and the NDoH 2024 Guidelines.
- Explore key ethical norms and standards, including relevance, scientific integrity, stakeholder engagement, risk–benefit ratio, fair selection, informed consent, ongoing respect, and researcher competence.
- Recognise the need for extra safeguards for vulnerable participants.

Module 6: Informed Consent

- Define informed consent and its process.
- Identify who can give informed consent (adults, minors, mentally impaired, emergency situations).
- Understand the elements and steps in the informed consent process, including special conditions for illiterate participants and minors.
- Learn about participant responsibilities and the role of impartial witnesses.

Module 7: Clinical Trial Protocol

- Understand what a clinical trial protocol is and its purpose (participant safety, data integrity).
- Review essential elements of a protocol: background, objectives, design, selection criteria, consent, assessment, treatments, data handling, statistics, ethics, finance, and publication.
- Learn about protocol amendments and approval processes.

Module 8: Recording and Reporting

- Define source documents and their importance.
- Learn about examples of source documents (CRFs, drug accountability, adverse event reports, correspondence, quality records).
- Understand investigator and sponsor responsibilities for data integrity, including ALCOAC principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete).
- Review correction procedures, electronic data capture, document retention, safety reporting, and progress/final reports.

Module 9: Essential Documents

- Identify the purpose of essential documents: compliance, participant protection, qualified personnel, auditing, and monitoring.
- Learn about the Trial Master File (TMF) and its role in effective monitoring and supervision.
- Review the list of essential documents and their retention requirements.
- Understand privacy and confidentiality requirements in clinical trials.