Good Clinical Practice (GCP) for Support Staff

Good Clinical Practice (GCP) in South Africa encompasses the ethical and scientific standards that guide the conduct of clinical trials involving human participants. It ensures participant safety, data integrity and regulatory compliance, ultimately contributing to the advancement of medical knowledge and the improvement of patient care.

Compliance with these guidelines is mandated.

Description

The **GCP Basic Course for Support Staff** is an introductory course designed for non-clinical support staff, including receptionists, drivers, data capturers, recruiters, counsellors, administrators, etc. Recognising their vital role at clinical research sites, the course provides essential GCP training. The course covers the basic concepts of clinical trials, GCP principles and their application when meeting or transporting clinical trial participants or completing documentation.

Available as classroom training

Content

Module 1: Introduction to Clinical Trials.
Module 2: Role-players in Clinical Trials.
Module 3: Introduction to GCP.
Module 4: SA GCP (SA GCP 2020).
Module 5: Ethics (NDoH 2024).
Module 6: Informed Consent.
Module 7: Clinical Trial Protocol.
Module 8: Recording and Reporting.
Module 9: Essential Documents.
Final Assessment.

Cost

Classroom - R3,600 (VAT incl.)

WHC Divisions | Projects:
Classroom - R2,700

For group discounts, please contact us at:
training@academicadvance.co.za

Duration

The classroom training is 1.5 days.

Target Audience

Non-clinical support staff, such as Counsellors, Fieldworkers, Recruiters, Data Capturers, Study Administrators, Drivers, etc.

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 Certificate of Completion, valid for 3 years.

CPD Points

CPD points will be issued with the certificate of completion.

In-House Training

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

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Learning Outcomes

Module 1: Introduction to Clinical Trials

- Define clinical trials and their purpose.
- Identify the phases of clinical trials.
- Understand the role of clinical trials in treatment development and safety.
- Recognise participant eligibility and informed consent processes.
- Understand the entry/enrollment and health monitoring procedures.
- Describe follow-up visit procedures and managing adverse events.
- Understand the final visit process and data analysis.

Module 2: Role-players in Clinical Trials

- Identify the Sponsor's role in clinical trials.
- Understand the Principal Investigator's (PI) responsibilities.
- Recognise the Study Coordinator's duties.
- Understand the roles of site staff.
- Define the research participant's role.
- Know the Monitor's responsibilities in protocol compliance.
- Understand the Research Ethics Committee's function.
- Recognise SAHPRA's role in regulating clinical trials.

Module 3: Introduction to GCP

- Understand GCP's role in protecting participants and ensuring data integrity.
- Identify GCP requirements: informed consent, risk-benefit assessment and protocol compliance.
- Learn the 13 principles of ICH-GCP.
- Understand the importance of ethics committee approval and data confidentiality.
- Recognise the role of quality control in clinical trials.

Module 4: SA GCP (SA GCP 2020)

- Understand SA GCP 2020's alignment with ICH GCP and NDoH 2024.
- Recognise SAHPRA's role in clinical trials.
- Identify ethical considerations for vulnerable populations.
- Understand Investigator and Sponsor responsibilities.
- Recognise essential clinical trial documents.
- Understand REC roles and informed consent.
- Explain the importance of data management and result dissemination.

Module 5: Ethics Guidelines

- Understand the South African Constitution's impact on healthcare and research rights.
- Apply ethical principles: respect for persons, beneficence, non-maleficence and justice.
- Recognise and protect vulnerable research participants.
- Ensure fairness in participant selection and research benefits.
- Understand the role of Research Ethics Committees.

Module 6: Informed Consent

- Define informed consent and its purpose in clinical trials.
- List the key elements of an informed consent document.
- Follow the steps in the informed consent process.
- Understand considerations for vulnerable participants (minors, mentally impaired, emergency situations).
- Recognise the role of impartial witnesses in informed consent for illiterate participants.

Module 7: Clinical Trial Protocol

- Understand the purpose and key components of a clinical trial protocol.
- Recognise the role of RECs and SAHPRA in protocol approval.
- Learn the process for protocol amendments and their impact on informed consent.
- Differentiate between protocol deviations and violations.

Module 8: Recording and Reporting Data

- Understand the importance of accurate data handling in clinical trials.
- Recognise source data and documents.
- Apply ALCOA-C principles to source data entries.
- Learn correction procedures for source data.
- Understand the purpose of Case Report Forms (CRFs).
- Familiarise with Electronic Data Capture (EDC) systems.
- Know document retention requirements.
- Understand safety and adverse event reporting.
- Recognise responsibilities for trial progress and outcome reporting.

Module 9: Essential Documents

- Understand the purpose of essential documents in clinical trials.
- Recognise the role of the Trial Master File (TMF) in trial documentation.
- Identify key documents in the TMF across trial stages.
- Understand the Investigator's Brochure (IB) and its importance.
- Learn privacy and confidentiality principles in clinical trials.
- Apply best practices to protect participant privacy and confidential data.