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 such as receptionists, drivers, data capturers, recruiters, counsellors and administrators, etc. These staff form an important role at the clinical research site and therefore also need to complete GCP training. The course covers the basic concepts of a clinical trial, GCP principles and how to apply these principles 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 (DoH Guidelines 2015).
Module 6: Informed Consent.
Module 7: Clinical Trial Protocol.
Module 8: Recording and Reporting.
Module 9: Essential Documents.
Final Assessment.

Cost

Classroom - R3,400 (VAT incl.)

WHC divisions | projects:
Classroom - R2,550

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.

(6 CPD points | 2 Ethics points)

In-house Training

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

academic advance

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Learning outcomes

Module 1: Introduction to Clinical Trials

- Define "clinical trial".
- Understand the importance of clinical trials.
- Understand the phases of a clinical trial.
- Explain the clinical trial process.
- Define "randomised control trials (RCT)".
- Define "placebo".
- Understand bias in clinical trials.
- Understand blinding in clinical trials.
- Understand the use of placebos as a control arm.

Module 2: Role-players in Clinical Trials

- Identify the role of the sponsor.
- Identify the role of the principal investigator.
- Identify the role of the study coordinator.
- Identify the role of the site staff.
- Identify the role of the research participants.
- Identify the role of the monitor.
- Identify the role of the Research Ethics Committee.
- Identify the role of the Statutory Bodies (SAHPRA).

Module 3: Introduction to GCP

- Describe the goals of GCP.
- Understand the development of GCP.
- Recall the formal evolution of ICH-GCP.
- Understand the International Conference on Harmonization (ICH).
- Understand the principles of ICH-GCP.

Module 4: SA GCP (SA GCP 2020)

- Understand the SA GCP framework.
- Understand key concepts in clinical trials.
- Understand managing recruitment of vulnerable participants.
- Recall regulatory authorities' roles and responsibilities.
- Understand the role of the sponsor.
- Understand the role of the investigator.
- Understand the investigator's brochure.
- Understand the essential documents to conduct a clinical trial.
- Understand other relevant considerations.

Module 5: Ethics Guidelines

- Explain the regulation of health research in South Africa.
- Explain ethics and responsible research.
- Understand the South African research context.
- Understand the guiding principle.
- Understand substantive norms and operational processes for ethics review.
- Understand research involving traditional medicine.
- Explain research on collectives.
- Explain the ethical basis for decision-making in the review process.
- Understand research on minors and women.
- Understand special topics.

Module 6: Informed Consent

- Define "informed consent".
- Recall the requirements for informed consent.
- Recall what the consent discussion and documentation should explain.
- Recall who approves the informed consent documentation.
- Explain who an impartial witness is.
- Explain where the signed informed consent is kept.

Module 7: Clinical Trial Protocol

- Define "clinical trial protocol".
- Understand the clinical trial process.
- Explain why clinical trials are necessary.
- Explain who approves clinical trials.
- Define "protocol amendments".
- Describe protocol deviations and violations.

Module 8: Recording and Reporting Data

- Describe ICH principles.
- Define "source data".
- Describe how source data complies with ALCOA-C principles.
- Describe how source data complies with the EMEA Proposal.
- Define "case report form (CRF)".
- Understand electronic data capture.
- Describe safety reports.
- Describe progress reports.
- Describe final reports.
- Describe adverse drug reporting.

Module 9: Essential Documents

- Define "essential documents".
- Describe Trial Master File (TMF).
- Describe the three stages of Trial Master File (TMF).
- List essential documents.
- Describe the Investigator's Brochure (IB).
- Explain privacy and confidentiality.
- Describe how to safeguard the privacy of clinical trial participants.