Good Clinical Practice (GCP) Basic Course for Clinical 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 **Good Clinical Practice (GCP) Basic Course for Clinical Staff** is an introductory course that provides a detailed overview of clinical research, the current ICH and SAGCP Guidelines, Doh 2015 – Ethics in Health Research Guidelines, as well as the process of conducting successful clinical trials from start to finish.

Available as classroom training

Content

Module 1: Introduction to Clinical Trials.
Module 2: Role-players in Clinical Trials.
Module 3: The Development of GCP (including ICH GCP).
Module 4: SA GCP (SA GCP 2020).
Module 5: Informed Consent.
Module 6: Ethics Guidelines (DoH 2015).
Final Assessment.

Cost

Classroom - R4,100 (VAT incl.)

WHC divisions | projects:
Classroom - R2,800

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

Duration

The classroom training is two full days (from 08h30 to 16h00).

Target Audience

Investigators, clinicians, study coordinators, scientists and project or site managers new to clinical trials.

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.

(12 CPD points | 2 Ethics points).

In-house Training

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

academic advance

Http://www.academicadvance.co.za
training@academicadvance.co.za
+27 11 274 9327/9263/9368
31 Princess of Wales Terrace, Parktown, 2193

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 and understand "placebos".
- Understand the use of placebos as a control arm.
- Understand bias in clinical trials.
- Understand blinding in clinical trials.

Module 2: Role-players in Clinical Trials

- Describe the role of the Sponsor.
- Describe the role of the Principal Investigator (PI).
- Describe the role of the Study Coordinator.
- Describe the role of the Site Staff.
- Describe the role of the Research Participants.
- Describe the role of the Research Ethics Committee (REC).
- Describe the role of the Statutory Bodies (SAHPRA).
- Describe the role of the Monitor.

Module 3: The Development of GCP (including ICH GCP)

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

Module 4: SA GCP (SA GCP 2020)

- Understand the reason for SA GCP guidelines.
- Understand the SA GCP framework and principals.
- 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.
- Explain clinical trial protocol and protocol amendments.
- Understand the investigator's brochure.
- Understand the essential documents to conduct a clinical trial.
- Understand other relevant considerations.

Module 5: 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 6: 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.