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 SA GCP Guidelines, NDoH 2024 – Ethics in Health Research Guidelines, as well as the process of conducting successful clinical trials from start to finish.

Available as classroom or virtual-led (for delegates residing outside of Gauteng) 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 (NDoH 2024).
Final Assessment.

Cost

Classroom - R4,350 (VAT incl.)
Virtual-led (for delegates residing outside of Gauteng) - R3,000 (VAT incl.)

WHC Divisions | Projects:
Classroom - R2,960
Virtual-led (for delegates residing outside of Gauteng) - R2,550

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.

In-House Training

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

academic advance

https://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

- Understand clinical research concepts.
- Differentiate between interventional and non-interventional studies.
- Recognise the purpose of clinical trials.
- Identify the phases of clinical trials.
- Comprehend trial processes.
- Prevent bias in clinical trials.
- Implement randomisation techniques.
- Apply blinding in trials.
- Understand the use of placebos in trials.

Module 2: Role-players in Clinical Trials

- Describe the roles and responsibilities of each clinical trial team member.
- Explain the role of the South African Health Products Regulatory Authority (SAHPRA).
- Understand the function of Research Ethics Committees (RECs) in ensuring ethical conduct.

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

- Recognise the historical development of Good Clinical Practice (GCP) Guidelines.
- Understand the key components of ICH GCP Guidelines.
- Apply ethical principles to ensure the safety and well-being of research participants.

Module 4: SA GCP (SA GCP 2020)

- Understand the SA GCP framework.
- Identify key concepts in clinical trials.
- Manage recruitment of vulnerable participants.
- Describe the roles of regulatory authorities, Investigators and Sponsors.
- Understand clinical trial protocols and protocol amendments.
- Recognise essential documents required for clinical trials.

Module 5: Informed Consent

- Understand the concept of informed consent.
- Identify the requirements for informed consent.
- Explain the content of the consent discussion and documentation.
- Recognise the role of an impartial witness.
- Understand the approval process for informed consent documentation.
- Know where signed informed consent forms are stored.

Module 6: Ethics Guidelines (NDoH 2024)

- Understand the regulation of health research in South Africa.
- Apply ethical principles to research in the South African context.
- Recognise substantive norms and processes for ethics review.
- Conduct research involving traditional medicine and collectivities.
- Address ethical considerations for research involving minors and women.

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial Sponsors.