Good Clinical Practice (GCP) Refresher

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 Refresher Course** is designed to assist clinical researchers to refresh their knowledge in the main concepts and principles of GCP. The course includes updates relating to current regulations and guidelines.

Available as classroom or online training

Content

Introduction: The Purpose of the GCP Refresher Course.
Module 1: The Principles of GCP [including ICH E6 (R2)].
Module 2: SA GCP 2020 Update.
Module 3: Ethics in Health Research (NDoH 2024).
Module 4: Latest Developments.
Final Assessment.

Cost

Classroom - R1,800 (VAT incl.)
Online - R1,180 (VAT incl.)

WHC Divisions | Projects:
Classroom - R1,200
Online - R1,000

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

Duration

The classroom training is 4.5 hours (from 08h30 to 13h00).

The online training takes approximately 4 to 4.5 hours to complete.

Target Audience

All clinical research personnel, who have previously completed a recognised GCP course: Investigators, Study Coordinators, Managers, 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.

academic advance

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Learning Outcomes

Module 1: The Principles of GCP [including ICH E6 (R2)]

- Understand the importance of GCP guidelines in clinical trials.
- Recognise the need for country-specific GCP guidelines.
- Apply the ICH-GCP principles in the practical setting of clinical trials.

Module 2: SA GCP 2020 Update

- Understand the updated SA GCP 2020 Guidelines, effective from October 2021.
- Apply the SA GCP 2020 Guidelines alongside the NDoH 2024 Guidelines for health research ethics.

Module 3: Ethics in Health Research (NDoH 2024)

- Understand the NDoH 2024 Ethics Guidelines in health research.
- Identify key ethical principles: respect, beneficence, non-maleficence and justice.
- Explain the importance of informed consent and voluntary participation.
- Differentiate between clinical and non-clinical research ethics.
- Recognise ethical guidelines for research with vulnerable populations.
- Understand the role of Research Ethics Committees (RECs).
- Apply ethical principles, focusing on risk-benefit distribution and stakeholder engagement.
- Address ethical considerations in animal research, biological materials and data science.

Module 4: Latest Developments

- Understand the ICH E6 (R3) revision and updates for clinical trials.
- Stay informed about SAHPRA's clinical trial guidelines and explore AI's role in improving trial efficiency and safety.
- Recognise AI's impact on personalised medicine and its applications in clinical trials.
- Understand the WHO Global Clinical Trials Forum's role and the benefits of decentralised clinical trials.

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.