Good Clinical Practice (GCP) Refresher Course

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Course Overview

Grounded in the South African Good Clinical Practice (SA GCP) 2020 Guidelines, the *GCP Refresher Course* is designed for clinical research professionals seeking to update and reinforce their understanding of Good Clinical Practice. The course provides a focused review of the ethical and scientific standards that govern the conduct of clinical trials involving human participants, with an emphasis on current regulatory developments and evolving best practices.

Delegates are also guided through key international and national frameworks that inform clinical research practice:

- The International Council for Harmonisation (ICH) E6(R3) Guideline for Good Clinical Practice, which outlines global standards for designing, conducting, recording, and reporting clinical trials.
- Ethics in Health Research: Principles, Processes and Structures (2024, Version 3.1), South Africa's national guideline governing ethical conduct in health research.

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 Refresher Certificate of Completion, valid for 3 years.

CPD Points

- CPD points will be issued with the certificate of completion.

Target Audience

The target audience includes clinical research professionals who have previously completed a recognised Good Clinical Practice course, such as principal investigators, sub-investigators, study coordinators, site managers, and research nurses.

It is also suitable for other members of the research team involved in the conduct, management, or oversight of clinical trials who wish to refresh their GCP knowledge and stay up to date with current guidelines.

Duration

- The classroom training is half a day (from 08h30 to 13h00).
- The online training takes approximately 4 to 4.5 hours to complete.

Cost

Classroom

WHC	R1,270.00	No Vat
Wits	R1,460.50	Vat Incl
Private	R1,897.50	Vat Incl

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

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academic advance
Wits Health Consortium (Pty) Ltd

Cost

Virtual (By prior arrangement)

WHC	R1,150.00	No Vat
Wits	R1,322.50	Vat Incl
Private	R1,520.30	Vat Incl

eLearning

WHC	R1,050.00	No Vat
Wits	R1,219.00	Vat Incl
Private	R1,265.00	Vat Incl

Learning Outcomes

Module 1: ICH E6(R3)

- Develop a broad understanding of the latest international Good Clinical Practice (GCP) standards and why they are important for clinical research.
- Grasp how global guidelines adapt to new technologies, trial designs, and participant needs.
- Become informed about the principles that underpin ethical research conduct, including participant safety and data integrity.
- Learn about the shift towards risk–based approaches and how digital tools are increasingly integrated into clinical trials.
- Appreciate the value of flexible, modular guidelines that can be applied across different research contexts.

Module 2: SA GCP 2020 Refresher (Chapters 1 – 5)

- Refresh foundational understanding of the ethical principles guiding clinical research in South Africa, including respect for persons, beneficence, and justice.
- Grasp the importance of participant protection and the processes for including and safeguarding vulnerable populations.
- Reinforce knowledge of roles and responsibilities in research, including investigators, sponsors, and oversight bodies.
- Understand the significance of protocol development, ethics approval, and site preparedness.
- Recognise the value of ongoing training and preparedness for all research team members.
- Appreciate the necessity of transparent communication and regulatory compliance throughout the research process.

Module 2: SA GCP 2020 Refresher (Chapters 6 – 10)

- Build awareness of key operational requirements for clinical trials, such as trial oversight, investigational product management, and reliable record–keeping.
- Understand the importance of proper documentation, accurate reporting, and robust quality assurance practices.
- Reflect on the roles and responsibilities of various stakeholders involved in clinical trials.
- Grasp how compliant trial conduct supports both the ethical and scientific integrity of research.
- Become informed about the expectations for maintaining essential documents, managing investigational products, and ensuring quality throughout the trial lifecycle.

Learning Outcomes

Module 3: GCP Monitoring, Auditing, and Inspection

- Become familiar with the processes of monitoring, auditing, and inspection, and why they are critical for maintaining high standards in clinical trials.
- Understand the need for thorough preparation, clear documentation, and readiness for regulatory review.
- Grasp the importance of maintaining essential documents, version control, and internal checks to ensure compliance.
- Learn to identify common pitfalls and challenges in GCP compliance, and how to avoid them.
- Appreciate the role of teamwork and ongoing training in supporting successful monitoring and inspection activities.

Module 4: Ethics in Health Research (NDoH 2024)

- Develop a deeper understanding of national ethical guidelines and their role in safeguarding research participants.
- Gain knowledge of key ethical principles, such as beneficence, justice, respect for persons, and the concept of Ubuntu.
- Become informed about the ethical review process, informed consent requirements, and data protection standards.
- Learn about emerging ethical issues in areas like genetics, artificial intelligence, and biobanking.
- Appreciate the importance of stakeholder and community engagement, and the need for a favourable balance between risks and benefits.

This module provides a high-level overview of the Ethics in Health Research: Principles, Processes and Structures guidelines, but delegates are still required to complete the full training. AA also offers a comprehensive Ethics in Health Research eLearning course for in-depth learning.