ADVANCED CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION (CLIC) COURSE 2026

Blended learning programme: Cape Town/on-site and virtual options
(venue to be confirmed)
August-September 2026

Fundisa African Academy of Medicines Development and Tiervlei Trial Centre have successfully offered their Clinical Investigator Certificate (CLIC) Course for 10 years.
The Advanced Clinical Investigator Certification (CLIC) Course 2026 is a comprehensive blended learning programme designed to equip **clinical investigators, clinical research staff, regulators, pharmacists and medical practitioners** with the latest competencies required for modern clinical research. Fully aligned with ICH E6 (R3) and E8 (R1), the course addresses the evolving demands of clinical trial practice, including ethics, operational excellence, digitalisation, AI, leadership, and future readiness.

With the adoption of ICH E6 (R3) on 6 January 2025, Good Clinical Practice has undergone a significant transformation. This revision introduces a flexible, principles-based framework applicable to a wide range of trial types. For the first time, it explicitly addresses requirements for data governance and computerized systems, as well as emerging approaches such as decentralized and pragmatic trials and the use of real-world data (RWD) (Annex 2 in development).

This course provides a structured and practical interpretation of these updates, with a strong emphasis on:

- Quality by Design (QbD)
- Risk-Based Quality Management (RBQM)
- Critical-to-Quality (CTQ) factors

Participants will gain a clear understanding of how to implement these concepts to ensure compliance, enhance trial efficiency, and maintain the highest standards of participant safety and data integrity.
In addition to regulatory and methodological foundations, the programme covers key enablers of future-ready clinical research, including digitalisation, artificial intelligence, operational excellence, and leadership. By integrating the principles of ICH E6 (R3) with the broader framework of ICH E8 (R1), this course prepares clinical research professionals to navigate complexity, address emerging challenges, and contribute to high-quality, ethically sound clinical trials in an increasingly data-driven environment.

Training on **NDoH 2024 guidelines, as referenced in SA GCP 2020, is now required by ethics committees in South Africa.**

CPD Accreditation: submitted

Fundisa
African Academy of
Medicines Development

TTC
Tiervlei | Trial | Centre

ADVANCED CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION (CLIC) COURSE 2026

MODULE 1: FOUNDATIONS OF MODERN GCP AND EVOLVING ETHICS

Date: 13 August 2026 Format: Face-to-face + virtual

Time	Speaker	Topic
07h30-08h15	**REGISTRATION and INTRODUCTION**	
08h15-09h45	Prof Keymanthri Moodley	The Evolution of Ethics in Research in the Context of ICH E6(R3)
09h45-11h00	Prof Bernd Rosenkranz	Overview of Medicines Development: The Global Regulatory Landscape
11h00-11h30		TEA BREAK
11h30-13h00	Dr Annalene Nel	Introduction to ICH E6(R3): The Paradigm Shift in GCP, Patient-Centricity, Proportionality, and Flexibility
13h00-13h45		LUNCH BREAK
13h45-15h15	Dr Haylene Nell	ICH E8(R1): Quality by Design, Critical-to-Quality Factors, and Inclusivity in Trial Design
15h15-15h30		TEA BREAK
15h30-17h00	Marzelle Haskins	Ethics and Regulatory Frameworks: DOH 2024 Guidelines and SA-GCP 2020

MODULE 2: OPERATIONAL EXCELLENCE AT TRIAL SITES

Date: 14 August 2026 Format: Face-to-face + virtual

Time	Speaker	Topic
08h00-09h00	Dr Zarinah Mohamed	Clinical Trial Site Competence: Roles of Investigators, Coordinators, and Site Staff
09h00-10h00	Dr Haylene Nell	Clinical Operations Process Standardisation for Quality Data
10h00-11h00	Prof Nobelungu Ngoloyi-Mekwa	Informed Consent in Modern Clinical Trials: Test of Understanding and e-Consent
11h00-11h15		TEA BREAK
11h15-12h15	Dr Tirhani Maluleka	Safety Reporting in Modern Clinical Trials
12h15-13h15	Prof Patrick Bouic	GCP-Compliant, Risk-Based Sample Lifecycle Management at the Clinical Trial Site
13h15-14h00		LUNCH BREAK
14h00-15h00	Shaakira Abrahams	Investigational Product Management in Modern Clinical Trials
15h00-15h15		TEA BREAK
15h15 -16h45	Dr Annalene Nel	Essential Records and Documentation for Data Integrity

ADVANCED CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION (CLIC) COURSE 2026

MODULE 3: PROTOCOLS AND DATA RELIABILITY

Date: 19 August 2026 Format: Virtual

Time	Speaker	Topic
15h00-16h00	Prof Kennedy Otwombe	Study Protocol Harmonisation: ICH M11 (CeSHarP)
16h00-17h00	Dr Annalene Nel	Reliable Data for Clinical Technical Documents

MODULE 4: DIGITALISATION AND DATA GOVERNANCE

Date: 26 August 2026 Format: Virtual

Time	Speaker	Topic
15h00-16h00	Marius Engelbrecht	Digitalisation of Clinical Trial Sites: e-Source, e-CTMS, Remote Monitoring, and Decentralised Models
16h00-17h00	Adriaan Kruger	Data Governance and Transparency: Ensuring Integrity, Privacy, and Compliance in Digital Systems

MODULE 5: AI IN CLINICAL TRIALS

Date: 02 September 2026 Format: Virtual

Time	Speaker	Topic
15h00-16h00	Prof Keymanthri Moodley	Good AI Practice in Clinical Research: What Investigators, Sponsors, and Sites Need to Know
16h00-17h00	Adriaan Kruger	AI in Clinical Trial Operations: Practical Use Cases, Limitations, and Implementation Readiness

MODULE 6: COMMUNITY ENGAGEMENT, DIVERSITY AND COMPLIANCE

Date: 09 September 2026 Format: Virtual

Time	Speaker	Topic
15h00-16h00	Dr Annalene Nel	Community Engagement and Diversity: Participant-Centred Approaches and Inclusive Research
16h00-17h00	Johan Heynz	Contracts, Stakeholder Agreements, and Insurance in Modern Clinical Trials: Legal and Operational Essentials

MODULE 7: LEADERSHIP AND RISK BASED QUALITY MANAGEMENT

Date: 16 September 2026 Format: Virtual

Time	Speaker	Topic
15h00-16h00	Renata Schoeman	Leadership: Building Quality Culture, Resilience, and Future-Ready Teams
16h00-17h00	Dr Annalene Nel	Risk-Based Quality Management and Clinical Quality Management Systems (CQMS)