

# ADVANCED CLINICAL INVESTIGATOR (and SITE STAFF) CERTIFICATION (CLIC) COURSE | 13 Aug -16 Sept 2026

Modern Clinical Research aligned with ICH E6 (R3), ICH E8 (R1), SA GCP 2020 and South African National Department of Health 2024 Guidelines

Hybrid programme | face-to-face and virtual delivery | Cape Town, South Africa



Fundisa African Academy of Medicines Development and Tiervlei Trial Centre have delivered the Clinical Investigator Certificate (CLIC) Course for 10 years.

The Advanced Clinical Investigator Certification (CLIC) Course 2026 is a comprehensive hybrid programme designed to equip **clinical investigators, clinical research staff, regulators, pharmacists and medical practitioners** with the competencies required for contemporary clinical research practice.

With adoption of ICH E6 (R3) in 2025, GCP has evolved toward more flexible, principles-based support for diverse trial designs, incl. decentralised and data-driven approaches. This course provides a practical interpretation of these updates, incl. emphasis on Quality by Design (QbD), Risk-Based Quality Management (RBQM) and Critical-to-Quality (CTQ) factors. The programme focuses on the practical application of these concepts to ensure regulatory compliance, improve efficiency, ensure safety and maintain data integrity.

It covers the regulatory and methodological foundations and explores the key enablers of contemporary clinical research, such as digitalisation, AI, operational excellence and leadership.

By integrating ICH E6 (R3) and ICH E8 (R1), the course offers an in-depth understanding of the conduct of modern clinical trials.

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

## CPD accreditation and registration deadline: to be confirmed

### MODULE 1: FOUNDATIONS OF MODERN GCP AND EVOLVING ETHICS

13 AUGUST | 08:00 - 17:00 SAST (UTC+02:00) | HYBRID

|                         |   |
|-------------------------|---|
| Prof Keymanthri Moodley | The Evolution of Ethics in Research in the Context of ICH E6 (R3)   |
| Prof Bernd Rosenkranz   | Overview of Medicines Development: The Global Regulatory Landscape  |
| Dr Annalene Nel         | Introduction to ICH E6(R3): The Paradigm Shift in GCP, Patient-Centricity, Proportionality, and Flexibility |
| Dr Haylene Nell         | ICH E8(R1): Quality by Design, Critical-to-Quality Factors, and Inclusivity in Trial Design                 |
| Marzelle Haskins        | Ethics and Regulatory Frameworks: DOH 2024 Guidelines and SA-GCP 2020                                       |

## MODULE 2: OPERATIONAL EXCELLENCE AT TRIAL SITES

14 AUGUST | 08:00 - 17:00 SAST (UTC+02:00) | HYBRID

|                              |  |
|------------------------------|--|
| Dr Zarinah Mohamed           | Clinical Trial Site Competence: Roles of Investigators, Coordinators, and Site Staff |
| Dr Haylene Nell              | Clinical Operations Process Standardisation for Quality Data                         |
| Prof Nobelungu Ngoloyi-Mekwa | Informed Consent in Modern Clinical Trials: Test of Understanding and e-Consent      |
| Dr Tirhani Maluleke          | Safety Reporting in Modern Clinical Trials   |
| Prof Patrick Bouic           | GCP-Compliant, Risk-Based Sample Lifecycle Management at the Clinical Trial Site     |
| Shaakira Abrahams            | Investigational Product Management in Modern Clinical Trials                         |
| Dr Annalene Nel              | Essential Records and Documentation for Data Integrity                               |

## MODULE 3: PROTOCOLS AND DATA RELIABILITY

19 AUGUST | 15:00 - 17:00 SAST (UTC+02:00) | VIRTUAL

|                 |   |
|-----------------|---|
| Dr Haylene Nell | Study Protocol Harmonisation: ICH M11 (CeSHarP) |
| Dr Annalene Nel | Reliable Data for Clinical Technical Documents  |



Dr Annalene Nel

## MODULE 4: DIGITALISATION AND DATA GOVERNANCE

26 AUGUST | 15:00 - 17:00 SAST (UTC+02:00) | VIRTUAL

|                    |   |
|--------------------|---|
| Marius Engelbrecht | Digitalisation of Clinical Trial Sites: e-Source, e-CTMS, Remote Monitoring, and Decentralised Models |
| Adriaan Kruger     | Data Governance and Transparency: Ensuring Integrity, Privacy, and Compliance in Digital Systems      |

## MODULE 5: AI IN CLINICAL TRIALS

2 SEPTEMBER | 15:00 - 17:00 SAST (UTC+02:00) | VIRTUAL

|                         |   |
|-------------------------|---|
| Prof Keymanthri Moodley | Good AI Practice in Clinical Research: What Investigators, Sponsors, and Sites Need to Know     |
| Adriaan Kruger          | AI in Clinical Trial Operations: Practical Use Cases, Limitations, and Implementation Readiness |

## MODULE 6: COMMUNITY ENGAGEMENT, DIVERSITY AND COMPLIANCE

9 SEPTEMBER | 15:00 - 17:00 SAST (UTC+02:00) | VIRTUAL

|                 |  |
|-----------------|--|
| Dr Annalene Nel | Community Engagement and Diversity: Participant-Centred Approaches and Inclusive Research                    |
| Johan Heyns     | Contracts, Stakeholder Agreements, and Insurance in Modern Clinical Trials: Legal and Operational Essentials |



Dr Haylene Nell

## MODULE 7: LEADERSHIP AND RISK BASED QUALITY MANAGEMENT

16 SEPTEMBER | 15:00 - 17:00 SAST (UTC+02:00) | VIRTUAL

|                 |  |
|-----------------|--|
| Renata Schoeman | Leadership: Building Quality Culture, Resilience, and Future-Ready Teams     |
| Dr Annalene Nel | Risk-Based Quality Management and Clinical Quality Management Systems (CQMS) |

## REGISTRATION FEES

| Option  | Course pathway   | Standard fee | Early-bird fee |
|---|--|--------------|----------------|
| <b>Option I: Modern Clinical Trial Operations</b>   | Modules 1 and 2, Cape Town on-site (full days; GCP/Ethics Certification) | R 6,000      | R 5,000        |
| <b>Option I: Modern Clinical Trial Operations</b>   | Modules 1 and 2, virtual   | R 5,000      | R 4,000        |
| <b>Option II: Modern Clinical Trials Advanced</b>   | Modules 3 to 7, virtual (five 2 hour modules)                            | R 7,000      | R 5,000        |
| <b>Option III: Full Advanced CLIC Certification</b> | Modules 1 to 7, hybrid   | R 12,000     | R 10,000       |
| <b>Option III: Full Advanced CLIC Certification</b> | Modules 1 to 7, virtual  | R 10,000     | R 8,000        |

All online participation is live only. No session recordings will be provided.

For group registration fees, please email [info@fundisa-academy.com](mailto:info@fundisa-academy.com).

### NAME & SURNAME:

### CONTACT DETAILS:

### AFFILIATION/ POSITION:

### MEAL PREFERENCE:

- NORMAL                      • VEGETARIAN                      ALLERGIES:

Kindly send your registration form and proof of payment to:

### BANKING DETAILS

ACCOUNT NAME:                      **Fundisa African Academy of Medicines Development**  
ACCOUNT NUMBER:                      **9290273284**  
BRANCH NAME:                      **ABSA Bank**  
BRANCH CODE:                      **632005**  
REFERENCE:                      **Name and Surname or invoice number**

1) Completion of this application means you will be liable for the full registration fee, as per the cancellation conditions below. 2) All cancellations must be in writing to [info@fundisa-academy.com](mailto:info@fundisa-academy.com). 3) Refunds generally not issued. Emergency requests to be addressed to: [info@fundisa-academy.com](mailto:info@fundisa-academy.com).