REFRESHER: CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION (CLIC) COURSE NHREC NDoH 2024 Ethics in Health Research Guidelines, SA GCP 2020, WMA Declaration of Helsinki 2024, ICH E6 (R3) and E8 (R1)

Nitida Wine Farm, Tygerberg Valley Road, Durbanville

15-16 May 2025

Fundisa African Academy of Medicines Development and Tiervlei Trial Centre have successfully offered their Clinical Investigator Certificate (CLIC) course for 10 years. This course is based on an internationally standardised syllabus established by PharmaTrain and the European Clinical Research Infrastructures Network (ECRIN). It provides a training platform on the increased complexity of medicines development and regulatory requirements for investigators, for site staff as well as regulatory and other scientists.

CLIC REFRESHER 2025 specifically addresses: NDoH Research guidelines 2024, SA GCP 2020, WMA Declaration of Helsinki, ICH E6 (R3) and E8 (R1) The NDoH 2024 guidelines, referenced in SA GCP 2020, emphasize the need for core ethical knowledge, high-quality data, and proper study preparation and conduct at investigational sites, currently not always included in GCP courses. ICH E6 (R3) Guideline for GCP was adopted on 6 January 2025. This major adaptation of GCP E6 (R3) provides principles and details for different types of clinical trials. For the first time, it addresses requirements to data governance and computerised systems and on decentralized & pragmatic trials and Real-World Data (RWD) (Annex 2, in preparation). The guideline thus presents a pivotal novel approach to clinical research by emphasizing Quality by Design (QbD), Risk-Based Quality Management (RBQM), and the critical-to-quality (CTQ) factor approach. It underlines the critical importance of maintaining high ethical standards, thorough record keeping, and a robust quality management system in the conduct of clinical trials to ensure the safety and rights of trial participants and the integrity of the trial data. Revision 3 of GCP must be read together with ICH Guideline E8 (R1) on general considerations for clinical trials which addresses key aspects and problems in clinical trials.

The target audience for this two-day programme includes all Investigators, clinical research staff, regulators, pharmacists and other medical practitioners.

SA GCP Refresher. HREC NDoH 2024 Research Ethics
CPD POINTS: Day 1= 8 Ethics, Day 2 = 8 Ethics

CPD Accreditation no: MDB015/841/04/2025

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Pre-course Competency Assessment (NHREC NDoH 2024 Guidelines)		
15 May 2025		
07h30-08h00	**REGISTRATION**	
08h00-09h00	Bernd Rosenkranz	Overview of the medicine development and regulation process
09h00-10h00	Haylene Nell	Research Methodology Quality by design. Ethical considerations
10h00 -10h30	TEA BREAK	
10h30-11h30	Marzelle Haskins	Summary of NHREC NDoH 2024 Research Ethics Guidelines
11h30-12h30	Marzelle Haskins	Guiding Principles for Ethical Research
12h30-13h30	LUNCH	
13h30-14h30	Marzelle Haskins	Norms and Operational Processes for Ethics Review
14h30-15h30	Marzelle Haskins	Human and Animal Biological Material and Data for Research
15h300-16h00	TEA BREAK	
16h00-17h00	Annalene Nel	Diversity in Clinical Trials. Community Engagement and Ethical Research conduct

16 MAY2025		
08h00-09h00	Keymanthri Moodley	Declaration of Helsinki. Historical and Current Perspectives
09h00-10h00	Keymanthri Moodley	Informed consent: Principles and Practice. SAGCP and NHREC NDoH 2024 Guidelines
10h00-10h30	TEA BREAK	
10h30-11h15	Keymanthri Moodley	AI in Clinical Trials: ethical considerations
11h15-12h00	Keymanthri Moodley	Data Protection, Privacy, and Confidentiality in Health Research
12h00-12h45	Adriaan Kruger	Data governance: Use of digital technologies in clinical trials and regulatory agency / legal compliance
12h45-13h30	LUNCH	
13h30-14h30	Annalene Nel	Essential records for reconstructing a clinical trial, with integrity
14h30 – 15h30	Jaco van Zyl	Risk proportional GCP. Doing things in a thoughtful way
15h30 – 16h00	TEA BREAK	
16h00 – 17h00	Annalene Nel	Clinical quality by design: Implementing Clinical Quality Management System (CQMS) for compliance and efficacy
Post -course COMPETENCY ASSESSMENT		

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15-16 May 2025

NAME & SURNAME:

CONTACT DETAILS:

CELL NO:
EMAIL ADDRESS:

AFFILIATION/ POSITION:

MEAL PREFERENCE:

☐ NORMAL ☐ VEGETARIAN ALLERGIES:

**Nitida Wine Farm is not Halaal certified

REGISTRATION FEES

R3 000.00 per day

Students (University certified): 50% discount on request

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**

Kindly send your registration form and proof of payment to:

Registration deadline:

1.) On completion of this application, you will be liable for the full amount of the registration fees subject to the cancellation conditions below. 2.) All cancellations must be sent in writing to: info@fundisa-academy.com. 3.) In general, no refunds will be issued for cancellations; any requests for a refund in an emergency should be addressed to: info@fundisa-academy.com.