

CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION COURSE SA GCP 2020

Nitida Wine Farm, Tygerberg Valley Road, Durbanville
24–28 APRIL 2023

The planning, preparing, and organising of clinical trials has become a highly complex task that includes important issues such as: the need to protect patients, generate reliable data, perform trials efficiently within short timelines, fulfil quality requirements according to current legislation and inspection requirements, and conduct clinical trials within budget to ensure sustainable business. Since COVID-19 emerged in 2020, it has caused unprecedented disruption of clinical trials. To protect patient safety and trial integrity, the pharmaceutical industry made strides to accelerate trial innovations such as digital tools and virtualization, with support from regulatory authorities. The increased complexity of medicines development and regulatory requirements require well-trained staff in industry, CROs and Regulatory Agencies. The 2018 SAHPRA draft guidance on “Capacity Building and Transformation in Clinical Trials Research in South Africa” requires public or private clinical trial sites to offer training at all staff levels. PharmaTrain and the European Clinical Research Infrastructures Network (ECRIN) have developed an international standardised Clinical Investigator Certification (CLIC) Course syllabus as training platform for investigators, site staff as well as regulatory and other scientists. Fundisa Academy African Academy of Medicines Development, together with Tiervlei Trial Centre, have successfully hosted CLIC courses in Cape Town and Johannesburg in line with the PharmaTrain syllabus since 2015.

Levels of training according to distinct responsibilities in the performance and evaluation of clinical trials:

CLIC LEVEL 1 + SA GCP 2020: Core knowledge on ethics, quality data, preparation and conduct of studies at investigational sites. The target audience for this two-day programme includes sub/co-investigators, study nurses, and study coordinators. **CPD POINTS 5 Ethics + 10 Clinical**

CLIC LEVEL 2: Knowledge in regulatory and managerial aspects, according to SA-GCP, international and national requirements. The target audience for this five-day programme includes principal investigators, clinical trial managers, and site managers. **CPD POINTS 3 Ethics +17 Clinical**



CPD ACCREDITATION NUMBER: MDB015/563/03/2023



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24 April 2023- LEVEL 1		
07h30-08h00	REGISTRATION	
08h00-09h00	Prof Bernd Rosenkranz	Overview of the medicine development process
09h00-10h00	Dr Haylene Nell	Introduction to clinical research methodology
10h00-10h30	TEA BREAK	
10h30-11h30	Marzelle Haskins	Introduction to the ethics of clinical research and GCP
11h30-13h00	Marzelle Haskins	Legislative framework and guidance for clinical research
13h00-14h00	LUNCH BREAK	
14h00-15h30	Dr Haylene Nell	Planning and preparation of a trial
15h30-16h00	TEA BREAK	
16h00-17h00	Dr Jaco van Zyl	Subject recruitment, enrolment, and retention
25 April 2023 LEVEL 1		
08h00-09h00	Dr Zarinah Mohamed	Site organization and management
09h00-10h30	Dr Zarinah Mohamed	Overview of in- trial procedures
10h30-11h00	TEA BREAK	
11h00-12h00	Dr Zarinah Mohamed	Overview of in- trial procedures
12h00-13h00	Savi Chetty-Tulsee	QA, monitoring, audits, and inspections
13h00-14h00	LUNCH BREAK	
14h00-15h30	Heila Engelbrecht	Document Management
15h30-16h00	TEA BREAK	
16h00- 17h00	Heila Engelbrecht	Document Management Workshop
LEVEL 1 COMPETENCY ASSESSMENT		
26 April 2023 - LEVEL 2		
07h30- 08h00	REGISTRATION	
08h00-11h00	Dr Kennedy Ot wombe	Basic concepts for designing and evaluating clinical trials
11h00-11h30	TEA BREAK	
11h30 -12h30	Dr Sanet Aspinal	Informed consent process
12h30-13h30	LUNCH BREAK	
13h30-15h30	Dr Haylene Nell	Study protocol content and writing
15h30-16h00	TEA BREAK	
16h00-17h00	Jaco Swart	Data collection and management, final reporting
27 April 2023- LEVEL 2		
08h00-09h30	Tirhani Maluleke	Safety Reporting and Data
09h30-11h00	Samuel Egjeyeh	Management of the investigational medicinal product
11h00-11h30	TEA BREAK	
11h30-13h00	Patric Bouic	Biological samples management
13h00-14h00	LUNCH	
14h00-15h00	Prof Bernd Rosenkranz	Clinical studies in special and vulnerable populations
15h00-15h30	TEA BREAK	
15h30-17h00	Dr Graham Ellis	Risk Management and Ethics of clinical research
28 April 2023 - LEVEL 2		
08h00-09h30	Johan Heyns	Contractual Agreement and Insurance
09h30-10h30	Jaco Swart	Budget Negotiation
10h30-11h00	TEA BREAK	
11h00-13h00	Hanlie Bester	Clinical Project Management
13h00-14h00	LUNCH BREAK	
14h00-15h00	Hanlie Bester	Clinical Project Management
LEVEL 2 COMPETENCY ASSESSMENT		

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NAME & SURNAME:**CONTACT DETAILS:**

CELL NO:

EMAIL ADDRESS:

AFFILIATION/ POSITION:**MEAL PREFERENCE:** NORMAL VEGETARIAN

ALLERGIES:

**Nitida Wine Farm is not Halaal certified

REGISTRATION FEES

- Option 1 R 4 000 (Level 1 only)
 Option 2 R 9 500 (Level 1 and 2)
 Option 3 R 6000 (Level 2 only)

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: nliebenberg@ttctrials.co.za

Registration deadline: **Thursday, 20 April 2023**

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: nliebenberg@ttctrials.co.za. 3.) Cancellations received before 20 March 2023 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 20 March 2023 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 20 March 2023 will not be entitled to any refund or credit, and such person will be liable for the full registration fee as per point (1) above. 7.) The Organizing Committee reserves the right to decline a request for a refund.