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 The 2018 SAHPRA draft guidance on "Capacity Building and Transformation in Clinical Trials Research in South Africa" requires public or private clinical trial sites to offer training at all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 ACCREDIDATION NUMBER: MDB015/563/03/2023

Tiervlei | Trial | Centre

Fundisa African Academy of Medicines Development

PharmaTrain MASTERING MEDICINES DEVELOPMENT CENTRE OF EXCELLENCE

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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 Otwombe	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	Kanshu Rajaratnam	CDM+ final reporting/Basic analysis of clinical trial data
27 April 2023- LEVEL 2		
08h00-09h30	Tirhani Maluleke	Safety Reporting and Data
09h30-11h00	Samuel Egieyeh	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	Haylene Nell	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		