CLINICAL INVESTIGATOR AND SITE STAFF CERTIFICATION COURSE SA GCP 2020

Nitida Wine Farm, Tygerberg Valley Road, Durbanville

09-13 Sep 2024

The planning, preparing, and organising of clinical trials have become a highly complex task that includes important issues such as: the need to protect participants generate reliable data, perform trials efficiently within short timelines, fulfil quality requirements according to current legislation and inspection requirements, utilisation of new technology and conduct clinical trials within budget to ensure sustainable business. 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 2022 SAHPRA guidelines on "Capacity Building and Transformation in Clinical Trials Research in South Africa" requires public or private clinical trial sites to offer training related to "Clinical Research and Regulatory Sciences". 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 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 clinical trials at investigational sites. The target audience for this two-day programme includes sub/co-investigators, study nurses, and study coordinators. CLIC 1: 12 Clinical, 2 Ethics

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 and co-investigators, clinical trial managers, and site managers. CLIC 2: 15 Clinical, 4 Ethics

CPD ACCREDITATION NUMBER: MDB015/1210/07/2024

Tiervlei | Trial | Centre

Fundisa African Academy of Medicines Development

Medinel Ethics • Safety • Quality

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09 September 2024 CLIC 1 (Day Registration CPD: 2 Ethical, 5 Clinical)		
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
11h30-12h30	Marzelle Haskins	Legislative framework and guidance for clinical research
12h30-13h30	LUNCH BREAK	
13h30-14h30	Dr Annalene Nel	Site organisation and management, Sponsor expectations
14h30-15h30	Dr Haylene Nell	Planning and preparation for a clinical trial
15h30-16h00	TEA BREAK	
16h00-17h00	Dr Annalene Nel	Community Engagement and Recruitment
10 September 2024 CLIC 1 (Day Registration CPD: 7 Clinical)		
08h00-010h30	Dr Zarinah Mohamed	Overview of in- trial procedures
10h30-11h00	TEA BREAK	
11h00-12h00	Dr Zarinah Mohamed	Overview of in-trial procedures
12h00-13h00	Dr Tirhani Maluleke	Introduction to Safety
12h30-13h30	LUNCH BREAK	
13h30-15h30	Dr Annalene Nel	Document Management, Workshop
15h30-16h00	TEA BREAK	
16h00-17h00	Dr Annalene Nel	QA, monitoring, audits, and inspections
LEVEL 1 COMPETENCY ASSESSMENT		
11 September 2024 CLIC 2 (Day Registration CPD: 1 Ethical, 6 Clinical)		
07h30- 08h00	REGISTRATION	
08h00-11h00	Dr Innocent Maposa	Basic concepts for designing and evaluating clinical trials
11h00-11h30	TEA BREAK	
11h30-13h00	Dr Haylene Nell	Study protocol development
13h00-14h00	LUNCH BREAK	
14h00-15h30	Dr Haylene Nell	Informed consent process
15h30-16h00	TEA BREAK	
16h00-17h00	Dr Annalene Nel	Data collection and management, final reporting
12 September 2024 CLIC 2 (Day Registration CPD: 1 Ethical, 5 Clinical)		
08h00-09h30	Dr Tirhani Maluleke	Safety Reporting and Data
09h30-10h30	Shaakira Abrahams	Management of the Investigational Medicinal Product
10h30-11h00	TEA BREAK	
11h00-12h30	Adriaan Kruger	Understanding Technology platforms in clinical Research
12h30-13h00	Marius Engelbrecht	e-CTMS, e-Source, site experience
13h00-14h00	LUNCH	
14h00-15h00	Prof Bernd Rosenkranz	Clinical Studies in vulnerable populations
15h00-15h30	TEA BREAK	
15h30-16h30	Prof Patrick Bouic	Biological Sample Management
13 September 2024 CLIC 2 (Day Registration CPD: 2 Ethical, 4 Clinical)		
08h00-09h00	Johan Heyns	Contractual Agreement and Insurance
09h00-10h30	Dr Sanet Aspinel	Financial and Budget Negotiation
10h30-11h00	TEA BREAK	
11h00-13h00	Prof Keymanthri Moodley	Ethics in Clinical Trials AI and Big Data
13h00-14h00	LUNCH BREAK	
14h00-16h00	Dr Annalene Nel	Management of Processes, Resources, Risk, Issues and Knowledge
LEVEL 2 COMPETENCY ASSESSMENT		

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09-13 SEP 2024

NAME & SURNAME:

CONTACT DETAILS:

CELL NO :
EMAIL ADDRESS :
HPCSA No. (for CPD Points) :
BILLING ADDRESS :
VAT NO :

AFFILIATION/ POSITION:

MEAL PREFERENCE:

NORMAL VEGETARIAN ALLERGIES:

Nitida Wine Farm is not Halaal certified

REGISTRATION FEES

- Option 1 R6 000 (Level 1 only)
- Option 2 R 12 000 (Level 1 and 2)
- Option 3 R 8 000 (Level 2 only)
- Option 4 R 2 500 (Daily Registration)

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: info@fundisa-academy.com

Registration deadline: **Thursday, 05 September 2024**

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.) Cancellations received before 08 August 2024 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 08 August 2024 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 08 August 2024 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.