

CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION COURSE

Nitida Wine Farm, Tygerberg Valley Road, Durbanville
11 – 15 MARCH 2019

The planning, preparing, and organising of clinical trials has become a highly complicated task that includes some important issues like: 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.

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 The 2018 SAHPRA draft guidance on "Capacity Building and Transformation in Clinical Trials Research in South Africa" requires public or private clinical trial sites to offer training at all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 since 2015.

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

CLIC LEVEL 1: Core knowledge in the preparation and conduct of studies at investigational sites. The target audience for this two-day programme includes sub/co-investigators, study nurses, study coordinators.

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 principle investigators, clinical trial managers, site managers.



CPD ACCREDITED

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11 MARCH - LEVEL 1	
07h30-08h00	REGISTRATION
08h00-09h00	Overview of the medicine development process
09h00-10h00	Introduction to clinical research methodology
10h00-10h30	TEA BREAK
10h30-11h30	Introduction to the ethics of clinical research and GCP
11h30-12h30	Legislative framework and guidance for clinical research
12h30-13h30	LUNCH BREAK
13h30-15h00	Planning and preparation of a trial
15h00-15h30	TEA BREAK
15h30-17h00	Subject recruitment, enrolment, and retention
12 MARCH- LEVEL 1	
08h00-09h30	Site organization and management
09h30-11h00	Overview of in- trial procedures
11h00-11h30	TEA BREAK
11h30-12h30	Overview of in- trial procedures
12h30-13h30	LUNCH BREAK
13h30-15h00	QA, monitoring, audits, and inspections
15h00-15h30	TEA BREAK
15h30-16h30	Introduction to safety
LEVEL 1 COMPETENCY ASSESSMENT	
13 MARCH - LEVEL 2	
07h30- 08h00	REGISTRATION
08h00-11h00	Basic concepts for designing and evaluating clinical trials
11h00-11h30	TEA BREAK
11h30-13h00	Study protocol
13h00-14h00	LUNCH BREAK
14h00-15h00	Data collection and management, final reporting
15h00-15h30	TEA BREAK
15h30-17h00	Informed consent process
14 MARCH - LEVEL 2	
08h00-09h00	Clinical studies in special and vulnerable populations
09h00-10h00	Biological samples management
10h00-10h30	TEA BREAK
10h30-11h30	Safety data
11h30-12h30	Management of the investigational medicinal product
12h30-13h30	LUNCH
13h30-16h00	Document Management
15 MARCH - LEVEL 2	
08h00-09h00	Ethics of clinical research
09h00-10h00	Insurance issues
10h00-10h30	TEA BREAK
10h30-12h00	Financial and contractual
12h00-13h00	LUNCH BREAK
13h00-15h00	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

PRE-REGISTRATION FEES (VALID UNTIL 31 DECEMBER 2018):

- Option 1 R3 375.00 (Level 1 only)
- Option 2 R8 500.00 (Level 1 and 2)
- Option 3 R5 500.00 (Level 2 only)

REGISTRATION FEES (VALID FROM 1 JANUARY 2019):

- Option 1 R4 000.00 (Level 1 only)
- Option 2 R9 500.00 (Level 1 and 2)
- Option 3 R6 000.00 (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 info@fundisa-academy.com

Registration deadline: **Thursday, 28 February 2019**

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 February 2019 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 08 February 2019. 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 08 February 2019. 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.