CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION COURSE

16 - 20 JULY 2018

Zulu Nyala Country Manor, 270E Third Avenue, Chartwell 2025, Gauteng

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 and regulatory requirements create a need for increasing levels of knowledge (Scientific, Methodological, Regulatory, & Organisational). In South Africa, investigators and site staff need to be trained according to international standards and recommendations. The 2018 SAHPRA draft guidance on "Capacity Building and Transformation in Clinical Trials Research in South Africa" requires public or private clinical trial sites to provide training, especially of previously disadvantaged personnel at all levels, that will enhance the full participation by such individuals in the trial conduct. PharmaTrain and the European Clinical Research Infrastructures Network (ECRIN) joined forces to establish a European investigator training infrastructure, called Clinical Investigator Certification (CLIC). Fundisa Academy African Academy of Medicines Development together with Tiervlei Trial Centre, have successfully hosted CLIC course in Cape Town, since 2015.

Different levels of training are related to distinct responsibilities in the performance of clinical trials:

CLIC LEVEL 1 covers the core knowledge in the preparation and conduct of studies at investigational sites. This two-day option is aimed at: sub/co-investigators, study nurses, study coordinators.

CLIC LEVEL 2 covers the knowledge in regulatory and managerial aspects required of principal investigators (and clinical trial managers), according to ICH-GCP definitions and national legislation. This five-day option is aimed at: principle investigators, clinical trial managers, site managers.

CPD ACCREDITED:

Tiervlei | Trial | Centre

Fundisa African Academy of Medicines Development

PharmaTrain MASTERING MEDICINES DEVELOPMENT CENTRE OF EXCELLENCE

16 JULY - 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
11h30-12h30	Marzelle Haskins	Legislative framework and guidance for clinical research
12h30-13h30	LUNCH BREAK	
13h30-15h00	Dr Essack Mitha	Planning and preparation of a trial
15h00-15h30	TEA BREAK	
15h30-17h00	Dr Essack Mitha	Subject recruitment, enrolment, and retention
17 JULY- LEVEL 1		
08h00-09h30	Farhaad Shaik	Site organization and management
09h30-11h00	Dr Margaré du Toit	Overview of in- trial procedures
11h00-11h30	TEA BREAK	
11h30-12h30	Dr Margaré du Toit	Overview of in- trial procedures
12h30-13h30	LUNCH BREAK	
13h30-15h00	Savi Chetty Tulsee	QA, monitoring, audits, and inspections
15h00-15h30	TEA BREAK	
15h30- 16h30	Dr Mada Ferreira	Introduction to safety
LEVEL 1 COMPETENCY ASSESSMENT		
18 JULY - LEVEL 2		
07h30- 08h00	REGISTRATION	
08h00-11h00	Dr Kennedy Otwombe	Basic concepts for designing and evaluating clinical trials
11h00-11h30	TEA BREAK	
11h30 -13h00	Dr Haylene Nell	Study protocol
13h00-14h00	LUNCH BREAK	
14h00-15h30	Dr Haylene Nell	Informed consent process
15h30-16h00		TEA BREAK
16h00-17h00	Dr Qasim Bhorat	Ethics of clinical research
19 JULY - LEVEL 2		
08h00-10h30	Heila Engelbrecht	Document management
10h30-11h00		COFFEE BREAK
11h30-12h30	Dr Mada Ferreira	Safety data
12h30-13h30		LUNCH
13h30-14h30	Prof Bernd Rosenkranz	Clinical studies in special and vulnerable populations
14h30-15h30	Jacky Cilliers	Management of the investigational medicinal product
15h30-16h00	TEA BREAK	
16h00-17h00	Prof Patrick Bouic	Biological samples management
20 JULY - LEVEL 2		
08h00-10h00	TBC	Data collection and management, final reporting
10h00-10h30	TEA BREAK	
10h30-11h30	Merissa Govender	Insurance issues
11h30-12h30	Dr Haylene Nell	Financial and contractual
12h30-13h30	LUNCH BREAK	
13h30-16h00	Farhaad Shaik	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:

REGISTRATION FEES:

☐ Option 1 R3 750.00 (Level 1 only)
☐ Option 2 R8 500.00 (Level 1 and 2)
☐ Option 3 R5 500.00 (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: **Friday, 06 July 2018**

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 06 July 2018 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 06 July 2018. 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 06 July 2018 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.