CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION COURSE

9 - 13 OCTOBER 2017

Cassia Conference Centre, Nitida Wine Farm, Tygervalley Road (M13), Durbanville, Cape Town

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. PharmaTrain and the European clinical research infrastructures network (ECRIN) joined forces to establish a European investigator training infrastructure, called Clinical Investigator Certification (CLIC).

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 Principle 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:

Level 1	11 General, 4 Ethics
Level 2	18 General, 9 Ethics

Tiervlei | Trial | Centre

Fundisa African Academy of Medicines Development

PharmaTrain MASTERING MEDICINES DEVELOPMENT CENTRE OF EXCELLENCE

09 OCTOBER - 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	Prof Lesley Burgess	Planning and preparation of a trial
15h00-15h30	TEA BREAK	
15h30-17h00	Prof Lesley Burgess	Subject recruitment, enrolment and retention
10 OCTOBER - LEVEL 1		
08h00-09h30	Mr Farhaad Shaik	Site organization and management
09h30-11h00	Dr Mada Ferreira	Overview of in- trial procedures
11h00-11h30	TEA BREAK	
11h30-12h30	Dr Mada Ferreira	Overview of in- trial procedures
12h30-13h30	LUNCH BREAK	
13h30-15h00	Ms Savi Chetty Tulsee	QA, Monitoring Audits and inspections
15h00-15h30	TEA BREAK	
15h30- 16h30	Dr Mada Ferreira	Introduction to safety
LEVEL 1 COMPETENCY ASSESSMENT		
11 OCTOBER - LEVEL 2		
07h30- 08h00	REGISTRATION	
08h00-10h00	Ms Heila Engelbrecht	Document Management
10h00-10h15	COFFEE BREAK	
10h15-11h15	Dr Haylene Nell	Study Protocol
11h15-11h30	TEA BREAK	
11h30-12h00	Dr Haylene Nell	Writing your own protocol
12h00-13h15	Dr Haylene Nell	Informed Consent Process
13h15-14h00	LUNCH	
14h00-15h00	Prof Patrick Bouic	Biological Samples Management
15h00-15h30	TEA BREAK	
15h30-17h30	Dr Graham Ellis	Ethics of clinical research
12 OCTOBER - LEVEL 2		
08h00-09h00	Dr Mada Ferreira	Safety data
09h00-10h00	Dr Hilary Johnstone	Basic concepts for designing and evaluating clinical trials.
10h00-10h30	TEA BREAK	
10h30-13h00	Dr Hilary Johnstone	Basic concepts for designing and evaluating clinical trials.
13h00-14h00	LUNCH BREAK	
14h00-15h30	Ms Shera Weyers	Data collection and management, final reporting
15h30-16h00	TEA BREAK	
16h00-17h00	Prof Sharon Kling	Clinical studies in special and vulnerable populations
13 OCTOBER - LEVEL 2		
08h00-09h30	Dr. Samuel Egieyeh	Management of the investigational medicinal product
09h30-10h00	TEA BREAK	
10h00-11h00	Dr Haylene Nell	Financial and contractual
11h00-12h00	Mr Jaco Swart	Application for a clinical research grant
12h00-12h30	Mr Johan Heynz	Insurance issues
12h30-13h30	LUNCH BREAK	
13h30-16h00	Ms Hanlie Bester	Clinical project management
LEVEL 2 COMPETENCY ASSESSMENT		

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NAME & SURNAME:

ADDRESS:

CONTACT DETAILS:

CELL NO:
EMAIL ADDRESS:

AFFILIATION/ POSITION:

QUALIFICATIONS:

MEAL PREFERENCE:

Please note that Cassia Restaurant is not certified Halaal

☐ NORMAL ☐ VEGETARIAN

ALLERGIES:

REGISTRATION FEES:

☐	Option 1	R3 500.00 (Level 1 only)
☐	Option 2	R8 500.00 (Level 1 and 2)
☐	Option 3	R5 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**

Kindly send your registration form and proof of payment to info@fundisa-academy.com

Registration deadline: **Friday, 29 September 2017**

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 22 September 2017 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 22 September 2017. 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 22 September 2017 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.