CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION

26 - 30 SEPTEMBER 2016

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 we need to train Investigator and Site Staff training according to international standards and recommendation. PharmaTrain and ECRIN joined forces and established an European investigator training infrastructure called CLIC (Clinical Investigator Certification). The Fundisa CLIC Course is based on the PharmaTrain CLIC Curriculum.

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 three/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

26 SEPTEMBER - 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	
10h30-12h30	Prof Lesley Burgess	Planning and preparation of a trial
12h30-13h30	LUNCH BREAK	
13h30-15h00	Dr Rinke Pretorius	Site organization and management
15h00-15h30	TEA BREAK	
15h30-16h30	Prof Keymanthri Moodley	Introduction to the ethics of clinical research and Good Clinical Practice
16h30-17h30	Prof Keymanthri Moodley	Legislative framework and guidance for clinical research
27 SEPTEMBER - LEVEL 1		
08h00-09h45	Savi Chetty-Tulsee Dr Mada Ferreira	Overview of in- trial procedures
09h45-10h00	TEA BREAK	
10h00-12h00	Savi Chetty-Tulsee	Quality assurance, Monitoring
12h00-13h00	LUNCH BREAK	
13h00-14h00	Savi Chetty-Tulsee	Audits and inspections
14h00-16h00	Dr Mada Ferreira	Subject recruitment, enrolment and retention
16h00-16h15	TEA BREAK	
16h15-17h15	Dr Mada Ferreira	Introduction to safety
LEVEL 1 COMPETENCY ASSESSMENT		

28 SEPTEMBER - LEVEL 2		
08h00-10h30	Dr Haylene Nell	Study protocol
10h30-11h00	TEA BREAK	
11h00-12h00	Dr Haylene Nell	Informed consent process
12h00-13h00	Prof Sharon Kling	Introduction to clinical studies in special and vulnerable populations
13h00-14h00	LUNCH BREAK	
14h00-15h00	Prof Patrick Bouic	Biological samples management
15h00-15h30	TEA BREAK	
15h30-17h30	Dr Graham Ellis	Ethics of clinical research
29 SEPTEMBER - LEVEL 2		
08h00-10h00	Wendy Wilcox	Document management
10h00-11h00	TBC	Management of the investigational medicinal product
11h00-11h30	TEA BREAK	
11h30-13h00	Dr Mada Ferreira	Safety data
13h00-14h00	LUNCH BREAK	
14h00-15h15	TBC	Basic concepts for designing and evaluating clinical trials
15h15-15h30	TEA BREAK	
15h30-17h00	TBC	Basic concepts for designing and evaluating clinical trials
30 SEPTEMBER - LEVEL 2		
08h00-10h00	Louise Marais	Data collection and management, final reporting
10h00-10h15	TEA BREAK	
10h15-11h45	Dr Haylene Nell	Financial and contractual
11h45-12h45	Nkejane Mofokeng	Insurance issues
12h45-13h30	LUNCH BREAK	
13h30-17h30	Brenda Wright	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:

☐ NORMAL ☐ VEGETARIAN ☐ HALAAL

ALLERGIES:

REGISTRATION FEES:

☐	Option 1	R3 200.00 (Level 1 only)
☐	Option 2	R8 000.00 (Level 1 and 2)
☐	Option 3	R4 800.00 (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: **31 August 2016**

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 10 August 2016 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 10 August 2016. 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 10 August 2016 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.