

CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION COURSE

26 - 30 SEPTEMBER 2016

Cassia Conference Centre, Ntida 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 Investigator and Site Staff need to be trained according to international standards and recommendation. PharmaTrain and European clinical research infrastructures network (ECRIN) joined forces to establish an European investigator training infrastructure called CLIC (Clinical Investigator Certification). The TTC/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



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	
10h30-11h30	Prof Keymanthri Moodley	Introduction to the ethics of clinical research and GCP
11h30-12h30	Prof Keymanthri Moodley	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
27 SEPTEMBER - LEVEL 1		
08h00-09h30	Dr Rinke Pretorius	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	Savi Chetty Tulsee	QA, Monitoring Audits and inspections
15h00-15h30	TEA BREAK	
15h30- 16h30	Dr Mada Ferreira	Introduction to safety
LEVEL 1 COMPETENCY ASSESSMENT		

28 SEPTEMBER - LEVEL 2		
08h00-9h30	Dr Haylene Nell	Study protocol
09h30-09h45	COFFEE BREAK	
09h45-11h15	Dr Haylene Nell	Informed consent process
11h15-11h45	TEA BREAK	
11h45-13h15	Dr Hillary Johnstone	Basic concepts for designing and evaluating clinical trials.
13h15-14h00	LUNCH	
14h00-15h00	Dr Hillary Johnstone	Basic concepts for designing and evaluating clinical trials.
15h00-15h30	TEA BREAK	
15h30-17h30	Dr Graham Ellis	Ethics of clinical research
29 SEPTEMBER - LEVEL 2		
08h00-10h00	Louise Marais	Data collection and management, final reporting
10h00-10h30	TEA BREAK	
10h30-12h30	Dr Mada Ferreira	Safety data
12h30-13h30	LUNCH BREAK	
13h30-14h30	Marlize Smuts	Management of the investigational medicinal product
14h30-15h30	Prof Sharon Kling	Clinical studies in special and vulnerable populations
15h30-16h00	TEA BREAK	
16h00-17h00	Prof Patrick Bouic	Biological samples management
30 SEPTEMBER - LEVEL 2		
08h00-10h00	Wendy Wilcox	Document management
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.