— CLIC —
Clinical Investigator (And Site Staff) Certification

CLIC Level 1: 23 - 24 March 2015
CLIC Level 2: 25 - 27 March 2015

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

CPD points

Level 1: 14 General, 2 Ethics

Level 2: 20 General, 4 Ethics

TIERVLEI TRIAL CENTRE

Fundisa
African Academy of Medicines Development

Recognised as centre of excellence by

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

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
- 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:

Level 1: Site staff/ sub-investigator

Level 2: Principal Investigator / Site Manager

Level 3: Sponsor Investigator

DIFFERENT LEVELS OF COMPETENCE

	OPTION 1: CLIC Level 1 2 days **R3200.00** **(Students R1800.00)**	OPTION 2: CLIC Level 1 & 2 5 days **R8000.00** **(Students R4200.00)**	OPTION 3: Level 2 only (no CLIC certification) 3 days **R4800.00 (StudentsR2400.00)**
LEVEL 1	**Core knowledge in the preparation and conduct of studies at Investigational Sites** • *Medical: Sub / Co-Investigators* • *Non-Medical: Study Nurse, Study Coordinator*	**Core knowledge in the preparation and conduct of studies at Investigational Sites** • *Medical: Sub / Co-Investigators* • *Non-Medical: Study Nurse, Study Coordinator*	
LEVEL 2		**Knowledge in Regulatory and Managerial aspects required of Principal Investigator (and Clinical Trial Managers) according to ICH-GCP definition and National Legislation** • *Principal Investigator* • *Clinical Trial Manager/ Site Manager*	**Knowledge in Regulatory and Managerial aspects required of Principal Investigator (and Clinical Trial Managers) according to ICH-GCP definition and National Legislation** • *Principal Investigator* • *Clinical Trial Manager/ Site Manager*

CLIC Level 1

Site Staff, Sub Investigators, PI's

LEVEL 1 DAY 1 23 MARCH 2014			
Time	**Topic**	**Content**	**Presenter**
07h30- 08h00	REGISTRATION		
08h00-09h00	**Overview of the medicine development process**	• The various steps of the medicines development process: sequence and duration	Prof Bernd Rosenkranz
09h00-10h00	**Introduction to clinical research methodology**	• Definition of the phases of clinical development (I-IV) and related research objectives • Structure of a clinical trial • Key elements of trial design • Definitions of parallel groups versus crossover, control, placebo, randomization, blinding, bias, intention-to-treat	Dr Haylene Nell
10h00-10h30	TEA BREAK		
10h30-12h30	**Planning and preparation of a trial**	• Review of protocol and related material • Interactions between investigator and sponsor (pre-study visit, investigator selection, budget and contract, initiation visit) • Submission to the ethics committee • Submission to national regulatory authorities • Preparation of study- related processes and documentation	Prof Lesley Burgess
12h30-13h30	LUNCH BREAK		
13h30-15h00	**Site organization and management**	• Evaluation of resources needed for the clinical trial • Organisation of the investigative site team • Organisation of a patient visit	Dr Rinke Pretorius
15h00-15h30	TEA BREAK		
15h30-16h30	**Introduction to the ethics of clinical research and Good Clinical Practice**	• History and justification of the regulations for subject protection • Origin and principles of ICH-GCP • Responsibilities of the various players	Prof Keymanthri Moodley
16h30-17h30	**Legislative framework and guidance for clinical research**	• International regulatory environment • Applicable national regulations	Prof Keymanthri Moodley
LEVEL 1 DAY 2 **24 MARCH 2014**			
08h00-09h45	**Overview of in- trial procedures**	• Source documents and essential documents • Subject visits, measurements and	Savi Chetty-Tulsee

		assessments • Completion, correction and control of the Case Report Form • Management of the investigational product	Dr Mada Ferreira
09h45-10h00			
10h00-12h00	**Quality assurance, Monitoring**	• Monitoring visits • Trial close-out • Basic concepts in quality management (Quality assurance incl. SOPs, quality control...	Savi Chetty-Tulsee
12h00-13h00	LUNCH BREAK		
13h00-14h00	**Audits and inspections**	• Monitoring versus audits versus inspections • Audit and inspection findings	Savi Chetty-Tulsee
14h00-16h00	**Subject recruitment, enrolment and retention**	• Challenge and strategy of recruitment • Different phases of recruitment and enrolment Patient information and informed consent process in adults and children • Randomisation in practice • Compliance check • Subject retention • Personal data confidentiality, patient privacy	Dr Mada Ferreira
16h00-16h15	TEA BREAK		
16h15-17h15	**Introduction to safety**	• Basic definitions and classification of adverse events (AE, SAE, ADR, SUSAR) • Reporting and management of adverse events, including un-blinding • Emergency situation handling	Dr Mada Ferreira
Level 1 Competency Assessment			

CLIC Level 2

Principal Investigator / Site Manager

LEVEL 2 DAY 1 25 MARCH 2014			
Time	**Topic**	**Content**	**Presenter**
08h00-10h30	**Study protocol**	• Structure and contents • Objectives and endpoints • Inclusion/exclusion criteria • Study diagram and flowchart • Measurements and assessments • Protocol amendments	Dr Haylene Nell
10h30-11h00	**TEA BREAK**		
11h00-12h00	**Informed consent process**	• Right of subjects information • Transmission and understanding of the subject	Dr Haylene Nell

		• Re-consent	
12h00-13h00	**Introduction to clinical studies in special and vulnerable populations**	• Children • Elderly subjects • Pregnancy and breast-feeding • Orphan diseases	Dr Harry Moultry
13h00-1400	**LUNCH BREAK**		
14h00-15h00	**Biological samples management**	• Use of biological markers for patient selection and evaluation of efficacy and safety • Shipment requirements • Archival in bio-banks	Prof Patric Bouic
15h00-15h30	**TEA BREAK**		
15h30-17h30	**Ethics of clinical research**	• Investigator responsibilities • Criteria for the ethical evaluation of studies (scientific validity, equipoise) • Risk-benefit assessment • Ethical review procedures • Use of placebo • Follow-on treatment • Conflicts of interest • Misconduct and fraud • Publication bias and clinical trial registries	Dr Graham Ellis
LEVEL 2 DAY 2 **26 MARCH 2014**			
8h00-10h00	**Document management**	• List of the essential documents generated before, during and after the trial • Investigator site file • Rules for archival • (Investigator versus sponsor file, duration)	Wendy Wilcox
10h00-11h00	**Management of the investigational medicinal product**	• Types of medication in a study • Packaging and labeling • Storage and handling • Return and accountability • Compliance monitoring	Tracey Coningham
11h00-11h30	**TEA BREAK**		
11h30-13h00	**Safety data**	• AE collection and assessment • SAE assessment and reporting	Tracey Coningham
13h00-14h00	**LUNCH BREAK**		
14h00-17h00	**Basic concepts for designing and evaluating clinical trials**	• Basic statistical concepts and definitions (confidence interval, statistical significance, odds ratio) • Types of study (observational versus experimental) and level of proof • Types of design (inter-patients, intra	Justin Harvey

		• patients, sequential) • Types of comparison (superiority, non-inferiority) • Various types of bias and measures to avoid them • Sample size calculation • Types of analysis (intention-to-treat versus per protocol) • Meta-analysis and evidence-based medicine • Subgroups and post- hoc analyses • Statistical significance and clinical interpretation	
LEVEL 2 DAY 3 27 MARCH 2015			
08h00-10h00	**Data collection and management, final reporting**	• Structure of the CRF • Data collection and documentation process • Central monitoring and quality control, data queries • Advantages and disadvantages of electronic data capture • Confidentiality and data protection • Final reporting	Jaco Swart
10h00-10h15	**TEA BREAK**		
10h15-11h45	**Financial and contractual**	• Investigator contract • Calculation of investigative site budget • Patient compensation and travel expenses • Invoicing	Dr Haylene Nell
11h45-12h45	**Insurance issues**	• Various types of insurance contracts and coverage • Variability of insurance • Regulations between countries	tbc
12h45-13h30	**LUNCH BREAK**		
13h30-17h30	**Clinical project management**	• Adequate resources and facilities • Project planning • Screening, recruitment and retention • Management of deviations and mistakes • Interaction with monitors, auditors and inspectors • Communication • Quality management • Training • Supervisory committees	Zoe Nell
Level 2 Competency Assessment			

Fundisa African Academy of Medicines Development
Tiervlei Trial Centre, Karl Bremer Hospital, Basement, Bellville, Cape Town, South Africa, 7530 • NPC 2014/104973/08
Tel: +27(0)219579400 | **Email:**haylenenell@ttctrials.co.za • rosenkranz@sun.ac.za |
Web:www.fundisa-academy.com
Banking Details: Fundisa African Academy of Medicines Development, Absa Bank, Savings Account Number 92-9027-3284, Branch Code 632005

Tiervlei Trial Centre
Karl Bremer Hospital, Basement
c/o Mike Pienaar Boulevard & Frans Conradie Drive
Bellville, Cape Town, 7530
Phone: +27(0)21 957 9400
Fax: +27(0)21 945 1836
E-mail: haylenenell@ttctrials.co.za