CLINICAL INVESTIGATOR (AND SITE STAFF) CERTIFICATION COURSE

Nitida Wine Farm, Tygerberg Valley Road, Durbanville

11 – 15 MARCH 2019

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 of medicines development and regulatory requirements require well-trained staff in industry, CROs and Regulatory Agencies. The 2018 SAHPRA draft guidance on "Capacity Building and Transformation in Clinical Trials Research in South Africa" requires public or private clinical trial sites to offer training at all staff levels. PharmaTrain and the European Clinical Research Infrastructures Network (ECRIN) have developed an international standardised Clinical Investigator Certification (CLIC) Course syllabus as training platform for investigators, site staff as well as regulatory and other scientists. Fundisa Academy African Academy of Medicines Development, together with Tiervlei Trial Centre, have successfully hosted CLIC courses in Cape Town and Johannesburg since 2015.

Levels of CLIC training according to distinct responsibilities in the performance and evaluation of clinical trials:

CLIC LEVEL 1: Core knowledge in the preparation and conduct of studies at investigational sites. The target audience for this two-day programme includes sub/co-investigators, study nurses, study coordinators.

CLIC LEVEL 2: Knowledge in regulatory and managerial aspects, according to SA-GCP, international and national requirements. The target audience for this five-day programme includes 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

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11 March - LEVEL 1		
07h30-08h00	REGISTRATION	
08h00-09h00	Prof Bernd Rosenkranz	Overview of the medicine development process
09h00-10h30	Dr Haylene Nell	Introduction to clinical research methodology
10h30-11h00	TEA BREAK	
11h00-12h00	Marzelle Haskins	Introduction to the ethics of clinical research and GCP
12h00-13h00	Marzelle Haskins	Legislative framework and guidance for clinical research
13h00-14h00	LUNCH BREAK	
14h00-15h30	Dr Haylene Nell	Planning and preparation of a trial
15h30-16h00	TEA BREAK	
16h00-17h00	Prof Bernd Rosenkranz & Farhaad Shaik	Subject recruitment, enrolment, and retention
12 March - 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	
13h30-14h30	Mohlabane Majoe	QA, monitoring, audits, and inspections
14h30-15h00	TEA BREAK	
15h00-16h00	Dr Rinke Pretorius	Introduction to safety
LEVEL 1 COMPETENCY ASSESSMENT		
13 March - 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	
14h00-15h00	Dr Haylene Nell	Informed consent process
15h00-15h30	TEA BREAK	
15h30-17h00	Dr Ahmed Abulfathi	Safety data
14 March - LEVEL 2		
08h00-09h00	Shera Weyers	Data collection, management and final reporting
09h00-10h00	Prof Bernd Rosenkranz	Clinical studies in special and vulnerable populations
10h00-10h30	TEA BREAK	
10h30-11h30	Prof Bernd Rosenkranz & Prof Patrick Bouic	Biological sample management and biomarkers
11h30-12h30	Dr Samuel Egieyeh	Management of the investigational medicinal product
12h30-13h30	LUNCH	
13h30-16h00	Heila Engelbrecht	Document management
15 March - LEVEL 2		
08h00-09h00	Dr Haylene Nell	Financial and contractual
09h00-10h00	Jaco Swart	Application for a clinical research grant
10h00-10h30	TEA BREAK	
10h30-11h30	Johan Heyns	Insurance issues
11h30-12h30	Dr Graham Ellis	Risk management and ethics of clinical research
12h30-13h30	LUNCH BREAK	
13h30-15h00	Hanlie Bester	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:

**Nitida Wine Farm is not Halaal certified

PRE-REGISTRATION FEES (VALID UNTIL 31 DECEMBER 2018):

☐ Option 1 R3 375.00 (Level 1 only)
☐ Option 2 R8 500.00 (Level 1 and 2)
☐ Option 3 R5 500.00 (Level 2 only)

REGISTRATION FEES (VALID FROM 1 JANUARY 2019):

☐ Option 1 R4 000.00 (Level 1 only)
☐ Option 2 R9 500.00 (Level 1 and 2)
☐ Option 3 R6 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 or invoice number**

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

Registration deadline: **Thursday, 7 March 2019**

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 08 February 2019 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 08 February 2019. 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 08 February 2019. 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.

SPEAKERS

Prof Bernd Rosenkranz, MD, PhD (Germany), FFPM, has a medical degree and is board certified Pharmacologist and Clinical Pharmacologist in Germany and South Africa and Fellow of the UK Faculty of Pharmaceutical Medicine (FFPM).

He has spent 23 years in industry, as Director of Clinical Pharmacology at Hoechst/Hoechst Marion Roussel in Germany, France and USA, Chief Medical Officer at ClinicalResearch in Berlin, Germany, and Vice President Clinical Development at Jerini, Berlin, Germany, where he was responsible for the world-wide clinical programme of icatibant in hereditary angioedema. From 2008 until 2016, he was head of the Division of Clinical Pharmacology, Stellenbosch University where he established the postgraduate programme in Pharmaceutical Medicine / Medicines Development (PharmaTrain Centre of Excellence).

Bernd Rosenkranz is President of the Fundisa African Academy of Medicines Development, board member of the South African Society for Basic and Clinical Pharmacology (SASBCP), and affiliate of the College of Clinical Pharmacologists (CMSA). He is member of several professional organisations, including the International Committee of the UK Faculty of Pharmaceutical Medicine, the International Federation of Associations of Pharmaceutical Physicians and Pharmaceutivcal Medicine (IFAPP), PharmaTrain Federation, and the PharmaTrain Certification Board for the Specialist in Medicines Development. He was chair of the Finance Committee of the 17th World Congress of Basic and Clinical Pharmacology (2014 in Cape Town), and is Finance Head in the regional committee of the 3rd World Conference on Pharmacometrics (WCoP, Cape Town, 6-9 April 2020).

His work has been presented in 115 original publications, 17 book chapters, 70 invited lectures/chairmanships, and 133 oral or poster presentations. He is Associate Editor of Frontiers in Pharmaceutical Medicine and Outcomes Research and of Journal of Medicines Development Sciences.

Bernd Rosenkranz is vice treasurer of the Manenberg Aftercare Centre, Cape Town.

Dr Haylene Nell is a medical doctor with postgraduate qualifications in Pharmacology and Epidemiology. She is the Head of Tiervlei Trial Centre CC (TTC), a dedicated clinical trial centre situated in Karl Bremer Hospital, founded in 2000 by Prof Frans Maritz and herself.

She is Vice President of Fundisa African Academy of Medicines Development (FAAMD), a non-profit organisation providing and promoting teaching and training of medicines development in South Africa and other African countries, and has organised 4 successful CLIC certification courses since 2015.

Haylene Nell is co-presenter of the Post Graduate Diploma in Pharmaceutical Medicine, Division of Clinical Pharmacology, University of Stellenbosch, and has an appointment as Extraordinary Senior Lecturer, Faculty of Health Sciences, University of Stellenbosch. She served as member of the Health Research Ethics Committee, Department Bioethics, Tygerberg Campus, University of Stellenbosch, and participates as presenter for the Faculty Advanced Ethics Training in South Africa (ARESA). She has been responsible as Principal Investigator for > 100 clinical trials and participated in > 400 trials since 1988 in various therapeutic areas, with a special focus on Asthma and COPD. Haylene has developed several protocols for single-centre studies, and was involved the data management, statistical analysis and clinical study reports for these “full service” studies.

Marzelle Haskins graduated from the University of Pretoria in 1996 with an LLB degree in law.

Since 1995 she was employed by Clindepharm International which was later bought by a Global Contract Research Organisation, Quintiles. Her duties included clinical trial monitoring and auditing of several multi-national clinical trials.

In 1998 she became involved with Pharma-Ethics Research Ethics Committee (REC) and in 2003 she left Quintiles for a full-time position at Pharma-Ethics, where she is responsible for managing the REC. She is also a voting member of the REC. In 2006 she was elected as a member of the National Health Research Ethics Council (NHREC) of South Africa and was re-elected in 2010. Marzelle was the chair of the NHREC working group for the Registration and Auditing of RECs in South Africa.

She is actively involved in training of Research Ethics Committee Members in Southern Africa and is currently a consultant for the Council on Health Research for Development where her duties include capacity building or RECs in Africa.

Farhaad Shaik has an Associates in Management Degree from the University of Cape Town's Graduate School of Business. He has operational and management experience across multiple industries and has been involved in Clinical Research since 2005 having participated in >150 protocols in various roles. He has provided workshops and consulting support to new and existing sites across South Africa to help them streamline processes and improve performance in pre-identified areas. He has managed research projects and sites in Johannesburg, Durban, Port Elizabeth, & Cape Town.

Farhaad has set-up a dedicated research facility & business brand from concept stage on paper to fully operational on the ground – being responsible for all aspects from clinical to business and everything else in-between. Additionally, he has also successfully project managed two research clinic site relocations which included design and building of facilities, prior to managing the physical relocation within budget and regulatory requirements and without adversely affecting operations or disrupting patient visits.

Dr Margaré du Toit qualified at the University of the Orange Free State in 1997.

Since joining Synexus Clinical Research SA (PTY) Ltd in 2010, she has been the principal and sub investigator on numerous studies and currently holds the position of Senior Research Physician/Medical Operations Manager for Gauteng.

She enjoys clinical research as no two studies are the same and each study brings its own challenges and opportunities to learn. Her fields of interest include, trauma, ICU, emergency medicine, and remote site medicine (and travel).

Mohlabane Majoe is a Director, Quality Management and Compliance at the International Partnership for Microbicides. He has over 23 years in clinical research. Mohlabane has experience in clinical trial administration, clinical monitoring, quality standards, training, safety case processing, and quality assurance. He has worked in South Africa, Benin, Burkina Faso, Cameron, Ghana, Ivory Coast, Kenya, Malawi, Mali, Nigeria, Uganda, Tanzania, and Zambia.

Mohlabane has led facilitation of GCP workshop and train over thousand health care professionals across Africa.

He participated in over 50 audits and supported local and foreign regulatory inspections. He previously worked for Pfizer, ICON and Aeras. He is a member of the South African Clinical Research Association (SACRA) and Research Quality Association (RQA).

Mohlabane holds a BSc. from the University of the North, QwaQwa Campus (now University of the Free State) and a B. Tech in Pharmaceutical Science from Tshwane University of Technology.

Dr Rinke Pretorius completed her medical degree at Stellenbosch University in 2004. Initially interested in Obstetrics and Gynaecology, she obtained the DIP Obs (SA) in 2006.

Her interest in clinical trials started when she realized how poorly trial patients were informed about the investigational product they were using.

In Jan 2007, she joined Helderberg Clinical Trials Centre in Somerset West, now known as Synexus Helderberg, until 2016.

Since Aug 2016 she is a Principal Investigator at Tiervlei Trial Centre.

Her field of interest is mainly in Adult metabolic diseases and pediatric asthma.

During her clinical trial career she has been exposed to several successful audits from sponsors, MCC (SAHPRA) and the FDA.

Dr Kennedy Otwombe is a biostatistician at the Perinatal HIV Research Unit, Chris Hani Academic Hospital (Soweto), University of the Witwatersrand.

He has authored or co-authored above 50 peer reviewed academic publications. He has experience working in HIV prevention and treatment studies as well as TB research. His other areas of interest include socio-behavioural research and mental health in HIV exposed and infected children, adolescents and adults. He is involved in several projects where he provides statistical input in study design, statistical analysis, grant writing as well as preparation of manuscripts. He has also been involved in the preparation of data safety and monitoring board (DSMB) reports for clinical trials and clinical study reports for drug registration. Currently, Kennedy is an academic editor for PLOS One and a member of several DSMB committees as a statistician for large trials currently running in South Africa funded by the NIH, the UK MRC and Bill and Melinda Gates foundation. He is involved in several network collaborations including HIV Vaccines Trials (HVTN) and Paediatric European Network for Treatment of AIDS (PENTA). Kennedy holds a joint appointment as a senior lecturer at the University of the Witwatersrand, School of Public Health (SPH) where he teaches biostatistics at the postgraduate level and supervises MSc and PhD research.

Dr Ahmed A Abulfathi is a consultant clinical pharmacologist and PhD candidate at Stellenbosch University, Cape Town, South Africa.

He received his MBBS degree from University of Maiduguri, Nigeria, MMed in Clinical Pharmacology from Stellenbosch University, FCCP (SA) from Colleges of Medicine of South Africa (CMSA).

He has 7-year clinical experience in Nigeria, 6-year experience in Clinical Pharmacology, Medicine and clinical research including clinical trials in South Africa. He also has 6-year experience of teaching both undergraduate and postgraduate health sciences students. He is a former member of the Stellenbosch University Health Research Ethics Committee. He is alumni of Novartis and University of Basel Next Generation Scientist Program (2017), Switzerland. He is a visiting scholar, Pharmacometrics group, Uppsala University, Sweden.

Shera Weyers earned her Bachelor of Science degree from the University of the Free State in 2001. She then continued her studies at the University of the Free State and obtained her Honours degree (B.Med.Sc, Hons) in 2002 and her Master's degree in Pharmacology in 2004. Shera Weyers has been involved in the CRO industry for over 12 years. In 2004 she joined Quintiles Data Management, where she was the Lead Data Manager on numerous clinical trials. During her time at Quintiles, she managed a team of Data Managers, obtained experience in various platforms, and worked on numerous global teams and focus groups. In 2013 she joined 3Degree Clinical Research and Consulting, as a Clinical Operations Manager, where she gained experience in regulatory submissions, monitoring, and managing the clinical operations, and CRAs on trials. In 2015 she joined TASK Applied Science as the Senior Data Manager. She is currently the Head of Data Management for Task Applied Science.

Dr Samuel Ayodele Egieyeh is a seasoned and experienced (over 20 years) pharmacist with B.Pharm (University of Lagos, Nigeria), M.Pharm (University of the Western Cape, Cape Town South Africa) and PhD in Bioinformatics (University of the Western Cape, Cape Town South Africa). He also has post-graduate certificates in clinical research and drug development from the University of Basel, Basel Switzerland. He started his career as a research fellow in 2001 at the Department of Pharmaceutics and Pharmaceutical Technology, National Institute for Pharmaceutical Research and Development (NIPRD), Abuja Nigeria where he was involved in the formulation, production and quality control of a herbal products (a remedy for sickle cell anaemia and malaria). He was later posted, as the pharmacist in charge, to the Antiretroviral Therapy Clinic where implemented various pharmaceutical care strategies for HIV infected clients under the Presidential Emergency Plan For AIDS Relief (PEPFAR) project. In 2007, he joined Howard University's Pharmacy and Continuing Education Centre under the Global HIV/AIDS Initiative Nigeria (GHAIN) project as a Pharmacy Specialist/Monitoring and Evaluation officer.

He is currently a lecturer at the Department of Basic pharmacology and Clinical Pharmacy, School of Pharmacy, University of the Western Cape, Cape Town South Africa. He is also a facilitator for the UK based Healthcare Learning's Masters in Regulatory Affairs. His area of expertise includes Preclinical Drug Development, Biostatistics and Big Data Analytics, Herbal Product Research and Development as well as Regulatory Affairs. His career goal is to contribute to the improvement of healthcare worldwide through research in drug design and development. His personal goals are to impart knowledge to the next generation through teaching and mentoring and to serve God and humanity.

Heila Engelbrecht is a qualified medical technologist.

After starting up the Covance Clinical Trial Laboratory in Cape Town, she joined Quintiles in February 1999 to pursue a career as a clinical monitor. During her employment, she had experience in all aspects of monitoring, from study start up to study close out. She has monitoring experience in most therapeutic fields. Specifically in CNS, Infectious Diseases, Cardiovascular, Urinary Incontinence, Allergic Rhinitis, Rheumatoid Arthritis, Respiratory, Diabetes and HIV Prevention, with a bit less experience in Oncology.

Heila has also taken on Clinical Lead and Project Management roles in Quintiles. She was involved on a daily basis in mentoring and training of junior CRAs. Heila was the mentor for 13 to 15 CRAs (requiring at least two onsite co-monitoring visits per year) and the Site Network Manager for approximately 60 sites conducting studies with Quintiles in Cape Town and Bloemfontein. She was one of two GCP experts at Quintiles, delivering approximately 25 GCP/SA GCP and other relevant courses per year to sites. During 2016 Heila consulted at various clinical trial sites on Site SOPs, adhering to SA GCP, Site File Content, Site Processes and Quality at site.

Heila has presented at two previous CLIC courses, as well as presenting at the PG Diploma in Medicines Development: Module III 2018. She is currently Clinical Operations Manager at PRA Health Sciences.

Jaco Swart received his Bachelor of Science degree in computer software engineering from UNISA in 2003. In 2012, he started a Master of Business Administration (MBA) degree on a part time basis, at the University of Stellenbosch, Business School. Jaco has successfully completed his MBA degree in 2016.

Jaco started his career in clinical trials in 2004 as a database programmer at Quintiles Data Management. At the end of 2005, he decided to further his clinical trial career as a financial administrator at the Tiervlei Trial Centre (TTC). Jaco was promoted to head the data management operations of a new subsidiary data management company of TTC, in 2007.

In 2009, he started working for Task Applied Science as their Financial Assistant, Data Manager and IT Support Engineer. His responsibilities included coordinating finances, managing data and supporting the IT infrastructure. In 2010, Jaco was promoted to Financial Manager and Head of Data Management. In 2015, he was promoted to the Head of Finance, Data Management and IT. After successfully completing his MBA degree in early 2016, Jaco became Director of the Finance, Data Management and IT departments for Task Applied Science.

Johan Heyns (LLB,ND. Personnel Management) is a human resource, labour and legal practitioner with more than 18 years practical experience.

He also obtained higher certificates from the Institute of Administration and Commerce in Business management, Management, Labour Relations, Personnel Management and Marketing Management. He is a Chartered Personnel Practitioner and admitted Advocate of the High court.

Johan has been working for Tiervlei Trial Centre as a consultant since 2009 and has reviewed the legal aspects of close to 100 clinical trials agreements.

Dr Graham Ellis is a Specialist Physician. He is currently Medical Director of Synexus Helderberg Clinical Research Centre, Somerset West.

He has more than 20 years' experience as an Investigator having started the Helderberg Clinical Trials Centre which was acquired by Synexus in 2014.

His medical interests are in the in the fields of Diabetes, Endocrinology, and Osteoporosis.

He has published and spoken at numerous local and international Scientific Meetings and acts as a reviewer for various local and international Medical Journals. He is also a published writer and has been shortlisted for two PEN/Studzinski Literary Awards

Hanlie Bester joined Aeras Global TB Vaccine Foundation NPO (now part of International Aids Vaccine Initiative) almost 5 years ago as a Senior Clinical Trials Manager. As CTM she is responsible for the management, oversight and execution of day-to-day operational activities for the conduct of these trials according to ICH GCP and relevant regulatory requirements. Hanlie is a subject matter expert on quality management, risk management and risk based monitoring and as a senior member of the clinical operations team plays a key role in mentoring and supporting her clinical operations colleagues.

Hanlie has worked in the clinical trial industry for 14 years of which 9 years were spent in clinical project management roles working for IAVI, Aeras, IQVIA and Covance (UK). Additionally she has over 3 years experience in business and project management working for Skilpadvlei Wine Farm and PriceWaterhouseCoopers.

Hanlie received her Masters Degree from the University of Stellenbosch. She obtained her PRINCE2 foundation and practitioner certification in 2008 and completed the "Management Programme for Non-Profit Organisations" short course presented by the University of Stellenbosch Business School in 2017.