WORKSHOP

NOVEL CLINICAL TRIAL METHODOLOGIES 2019

25 February 2019

Innovative drug development methods and tools are developed and used by pharmaceutical industry, clinical research organisations, public/private partnerships, and academic researchers to decrease cost and time to market and to increase the probability of success of pharmaceuticals R&D. Novel clinical trial methodologies based on stringent scientific criteria have gained acceptance for successful regulatory approval. The US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have established formal advice procedures for qualification of such methodologies, in consultation with the scientific community.

This workshop presented by Fundisa African Academy of Medicines Development and Pharmacometrics Africa will provide insight into the use of modelling and simulations, adaptive trial designs and real-world effectiveness studies by local and international experts with hands-on experience. By meeting with fellow local clinical trial researchers, the workshop offers a unique networking opportunity for drug, medical device and biotech companies, clinical trial professionals such as project managers, CRAs, medical writers, statisticians, and regulatory affairs professionals.

Programme Committee:

Elizabeth Allen, BSc (Hons), MPH, Cert Human Pharmacology, PhD
Head of Clinical Research, CCOAT and Lead, Global Health Trials South Africa, Division of Clinical Pharmacology, Department of Medicine, University of Cape Town, South Africa

Prof Andreas Diacon, MD, PhD
Founder and CEO, TASK Applied Science (TASK), Cape Town, South Africa

Prof Colin Pillai, PhD
Division of Clinical Pharmacology, Department of Medicine, University of Cape Town, Pharmacometrics Africa NPC, Cape Town, South Africa and CPPlus Associates, Binningen, Switzerland

Prof Bernd Rosenkranz, MD, PhD, FFPM
President, Fundisa African Academy of Medicines Development and Professor emeritus, Division of Clinical Pharmacology, Department of Medicine, Stellenbosch University, South Africa

Phumla Sinxadi, MBChB, DA (SA), MMed, Cert Human Pharmacology, PhD
Senior Lecturer, Division of Clinical Pharmacology, Department of Medicine, University of Cape Town, South Africa

Speakers:

Prof Leon Aarons, BSc, MSc, PhD, Manchester Pharmacy School, University of Manchester, UK

Florian Marx, MD, MSc, PhD, Senior Researcher, South African Centre for Epidemiological Modelling and Analysis (SAMCEA) & Desmond Tutu TB Centre, Faculty of Medicine and Health Sciences, Stellenbosch University

Lindi Mathebula, BSc Hons, BTech Pharmaceutical Science, BSc, Scientist, Cochrane South Africa, South African Medical Research Council, Cape Town, South Africa

Mireille Muller, BSc, MSc, PhD, Regulatory Policy Director, Novartis Pharma AG, Basel, Switzerland

Duduzile Ndwandwe, PhD, MSc, BSc Hons, BSc, Senior Scientist, Cochrane South Africa, South African Medical Research Council, Cape Town, South Africa

Prof Joel S. Owen, PhD, VP Strategic Modelling & Simulation, Cognigen Corporation and Adjunct Professor, College of Pharmacy, Union University, Jackson, Tennessee, USA

Jay Park, MSc, PhD, Senior Scientist MTEK Sciences, Vancouver, Canada

Natasha Pillai, MBChB, MSc, Engagement Manager, IQVIA, Basel, Switzerland

Prof Helmuth Reuter, MBChB, FCP (SA), MMed (Int), FRCP (Edinb), PhD, Head, Division of Clinical Pharmacology, Department of Medicine, University of Stellenbosch, South Africa

Enquiries: info@fundisa-academy.com

Fundisa African Academy of Medicines Development

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PROGRAMME

25 FEBRUARY 2019		
08:30 - 09:00	Bernd Rosenkranz	Welcome and introduction
	Modelling and Simulations	**Chair: Phumla Sinxadi**
09:00 - 09:45	Florian Marx	Modelling the dynamics and control of infectious diseases: The example of tuberculosis
09:45 - 10:30	Leon Aarons	Pharmacokinetic and pharmacodynamic modelling
10:30 - 11:00		TEA BREAK
11:00 - 11:45	Joel S. Owen	Novel clinical trial designs for optimizing parameter estimation in malaria disease-drug models
11:45 - 12:00	Lindi Mathebula & Duduzile Nwandwe	South African clinical trials database - an update
12:00 - 12:15	Elizabeth Allen	Global health working group for the Trials Methodology Research Partnership
12:15 - 13:45		LUNCH BREAK
	Clinical Trial Designs	**Chair: Colin Pillai**
13:45 - 14:30	Jay Park	Improving efficiency and quality in clinical trials in global health research: Adaptive trial designs and master protocols
14:30 - 15:15	Natasha Pillai	Real world data and evidence in clinical trial design
15:15 - 15:45		TEA BREAK
15:45 - 16:30	Helmuth Reuter	Investigator experience: Role in trial design, conduct, analysis and reporting
16:30 - 17:15	Mireille Muller	Innovative trial designs: Engaging with regulators, ethic committees and patients
17:15 - 17:45	All Speakers	General discussion: Novel clinical trial methodologies - International and African perspectives
17:45 - 18:00	Colin Pillai	Closing remarks

VENUE: Lagoon Beach Hotel, Courtyard 1, 1 Lagoon Gate Drive, Milnerton, Cape Town

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SPEAKERS

Prof Leon Aarons is Professor of Pharmacometrics in the Manchester Pharmacy School, the University of Manchester. He is a member of the scientific board of the Centre of Applied Pharmacokinetic Research, a research initiative set up within the School of Pharmacy in 1996 to provide an academic centre of excellence for research and training in DMPK engaged in problems of generic interest to the pharmaceutical industry and sponsored by major pharmaceutical companies. His major research interests lie in the area of pharmacokinetic and pharmacodynamic modelling and he has a world-wide reputation in the area of population pharmacokinetics with applications in drug development and drug utilization in a number of disease states including tropical diseases such as malaria. He is a member of the British Pharmacological Society, a founding member of the United Kingdom Pharmacokinetic Discussion Group and a member of the organizing committee of the Population Approach Group Europe. He is on the editorial boards of a number of journals including Emeritus Editor of the Journal of Pharmacokinetics and Pharmacodynamics. He has supervised more than 40 postgraduate students many of which have gone onto positions in academia and the pharmaceutical industry. For more than 20 years he has been teaching pharmacokinetics and pharmacodynamics courses in Europe, Australasia, The United States and Africa.

Dr Elizabeth Allen is a pharmacist with an MPH and PhD Clinical Pharmacology. She has worked in clinical research in the UK and South Africa since 1995, initially for pharmaceutical companies and CROs, thereafter managing academic clinical research in multiple African countries. She currently heads clinical research operations for the University of Cape Town (UCT) Collaborating Centre for Optimising Antimalarial Therapy, is Scientific Coordinator for the World Wide Antimalarial Resistance Network pharmacology group and Southern African Centre, and leads capacity development efforts for Global Pharmacovigilance and Global Health Trials South Africa. She has an academic interest in clinical trial conduct methodology research, focused on participant-reported outcomes data and IPD safety meta-analyses, and is co-lead of a new Global Health Working Group for the UK MRC-funded Trials Methodology Research Partnership.

Dr Florian Marx is a Senior Researcher at SACEMA and the Desmond Tutu TB Centre (DTTC), Faculty of Medicine and Health Sciences of Stellenbosch University. He coordinates a joint SACEMA-DTTC Tuberculosis Modelling Partnership and Research Programme and leads the Working Group Data Analysis and Modelling (WGDAM). Before joining SACEMA, he received a PhD degree at Stellenbosch University (2018) and completed a research fellowship at Harvard Medical School (2014) and Yale School of Public Health (2015-16). He received a Masters Degree in Epidemiology from the London School of Hygiene and Tropical Medicine (2009) and a Medical Degree from Charité Berlin (2007). His research focusses on the epidemiology of tuberculosis and the public health impact of TB control interventions with a particular focus on high-incidence settings.

Dr Mireille Muller is currently Regulatory Policy Director at Novartis, focusing on clinical trials, advanced therapy medicinal products (cell and gene therapies), personalised medicines. She is also supporting efforts towards digitalisation in clinical research. She is involved in several IMI projects (IMI PREFER on patient preference elicitation for decision making by regulators and health technology bodies and IMI ConCEPTION 'Building an ecosystem for better monitoring and communicating safety of medicines use in pregnancy and breastfeeding: validated and regulatory endorsed workflows for fast, optimised evidence generation'). Mireille is part of several EFPIA groups such as the Clinical Development Expert Group, Centralised Procedure and Scientific Advice (CPSA) group and is on the EBE Personalised Medicine working group. She is part of the EuropaBio group on advanced therapy medicinal products. She is also part of several other groups such as eClinical Forum, DIA patient engagement all related in improving clinical research and patients' rights and well-being. Mireille is providing training on a regular basis both internally and at university level and chaired several sessions at DIA conferences.

Prof Joel S. Owen is VP, Strategic Modeling and Simulation of Cognigen Corporation, a Simulations Plus Company, and is Adjunct Professor in the College of Pharmacy, Union University. His research focuses on applications of quantitative methods for the development and use of therapeutic compounds. Joel has 25 years of experience in the application and research of population pharmacokinetic and pharmacodynamic methods, the majority of that time has been in the pharmaceutical industry, with 10 years in the College of Pharmacy. Throughout his career, Joel has sought to teach and mentor others in the use of modeling and simulation to inform decision making. He has taught a NONMEM short-course at Makerere University, Kampala, Uganda and in other settings on multiple occasions and founded a postdoctoral fellowship program in pharmacometrics at Union University.

Dr Jay Park is a Senior Research Scientist at MTEK Sciences and a lecturer at McMaster University within the Department of Health Research Methodology, Evidence, and Impact. He leads and manages trial design planning, protocol development, and implementation at MTEK Sciences, a global health analytical firm that acts as the Trials Service Unit for the Bill Melinda Gates Foundation. At McMaster University, he developed and delivered the first formally approved graduate level course on adaptive trial designs and master protocols. His research interests involve adaptive trial designs, master protocols, and precision public health approaches in context of low- and middle-income countries.

Dr Natasha Pillai is responsible for overseeing a number of studies using real world data (RWD) from a European registry collaboration and a large RWD platform in Ophthalmology. She also co-leads innovative projects leveraging RWD for advanced analytics and decision support tool development.

Prior to joining IQVIA, Natasha worked clinically within the UK National Health Service (NHS). She has also been responsible for critical appraisal and indirect treatment comparisons to develop clinical guidelines commissioned for the National Institute for Health and Care Excellence (NICE). Natasha holds a medical degree (MBChB) from the University of Manchester and an MSc in Public Health from the London School of Hygiene and Tropical Medicine.

Prof Helmuth Reuter is a South African professor of internal medicine and is currently the Head of the Division of Clinical Pharmacology at the Faculty of Medicine and Health Sciences at the University of Stellenbosch. He is also a director of the Winelands Medical Research and the Winelands Rheumatology Centre, which forms part of the Institute of Orthopaedics and Rheumatology (IOR). Prior to his ten year stint in the private sector, he headed the Divisions of Rheumatology and Infectious Diseases at Tygerberg Hospital and was the director of the Ukwanda Centre for Rural Health.

He studied medicine at the University of Stellenbosch and specialised thereafter in internal medicine, cardiology, rheumatology and infectious diseases spending time in London, Cambridge, Norwich, Paris and at the National Institutes of Health (NIH) in Bethesda, Maryland (USA).

His PhD was on the pathogenesis, diagnosis and management of large pericardial effusions allowing him to conduct research in the fields of epidemiology, immunology, HIV, tuberculosis, connective tissue diseases and cardiology. He has published widely, but his main emphasis has been dissemination of knowledge to those that needed it most, namely practising health care workers.

He is a member of the American Academy of Science, a Fellow of the Royal College of Physicians of Edinburgh, Fellow of the Royal Society of Tropical Medicine and Hygiene, an Associate of the College of Clinical Pharmacology and a former winner of the MM Suzman medal for the best candidate in the FCP internal medicine examination in 1996 and also the Stellenbosch University's Faculty award for the best postgraduate student (MMed) in 2006.

His main research interests are the therapeutic management and cardiovascular involvement of SLE and immune-mediated, inflammatory arthritides, management of chronic pain, as well as the optimisation of anti-tuberculous and other anti-infective therapies in adults and children. His research includes community-based intervention studies, randomised clinical trials, clinical, laboratory based drug-drug interaction and pharmacokinetic studies.

He has authored or co-authored more than 100 publications, written 6 chapters in books and he has contributed as a speaker at many national and international conferences.

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.