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

Colin Pillai, PhD
CPPlus Associates, Binningen, Switzerland and Pharmacometrics Africa NPC, Cape Town, South Africa

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

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

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

Venue: TASK Headquarter Building, Smith Street, Glenlily, Cape Town

Enquiries: info@fundisa-academy.com

Fundisa African Academy of Medicines Development

pharmacometrics africa

PharmaTrain MASTERING MEDICINES DEVELOPMENT CENTRE OF EXCELLENCE

PROGRAMME

25 FEBRUARY 2019		
08:30 - 09:00	Bernd Rosenkranz	Welcome and introduction
09:00 - 12:15	**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 - 12:15		Project presentations
12:45 - 13:30		LUNCH BREAK (with viewing of poster presentations)
13:30 - 17:45	**Clinical Trial Designs**	**Chair: Colin Pillai**
13:30 - 14:15	Jay Park	Improving efficiency and quality in clinical trials in global health research: Adaptive trial designs and master protocols
14:15 - 15:00	TBD	Real world evidence studies
15:00 - 15:30		TEA BREAK
15:30 - 16:15	Helmuth Reuter	Investigator experience: Role in trial design, conduct, analysis and reporting
16:15 - 17:00	TBD	Novel clinical trial designs: Regulatory expectations
17:00 - 17:45		Project presentations
17:45 - 18:00	Elizabeth Allen	Global health working group for the UK MRC hubs for trial methodology research

CALL FOR ABSTRACTS:

Delegates are welcome to submit abstracts for poster presentation; selected abstracts will be invited for additional oral presentation (10 minutes). Submissions must be sent by email to info@fundisa-academy.com. All abstracts must be prepared according to the template provided below.

NOVEL CLINICAL TRIAL METHODOLOGIES 2019

ABSTRACT TITLE

Authors (Example: H. Potter[1]; presenting author underlined)
Affiliation(s) (Example: [1]Division of Irreproducible Results, Hogwarts University, South Africa)
Correspondence: email address

Introduction

Methods

Results

Discussion

References

Instructions: Text must be in Arial 10; the maximum length of 1 page must not be exceeded.

WORKSHOP

NOVEL CLINICAL TRIAL METHODOLOGIES 2019

25 February 2019

NAME AND SURNAME:

ADDRESS:

AFFILIATION/POSITION:

QUALIFICATIONS:

CONTACT DETAILS:

EMAIL ADDRESS:

CONTACT NUMBER:

MEAL PREFERENCE

☐ NORMAL ☐ VEGETARIAN ALLERGIES:

REGISTRATION FEES:	1 DAY WORKSHOP
Academia and Government	R 1,500.00
Industry, CRO's, and others	R 5,000.00

ACCOUNT NAME :	**Fundisa African Academy of Medicines Development**
ACCOUNT NUMBER:	**9290273284**
BRANCH NAME :	**ABSA Bank**
BRANCH CODE:	**632005**
TYPE OF ACCOUNT :	**Savings Account**
REFERENCE:	**Name and Surname**

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

Submission deadline for registration and abstracts: **18 February 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: Celia van der Merwe (info@fundisa-academy.com). 3.) Cancellations received before 1 February, 2019 will receive a refund less a 10% administration fee. 4.) No refunds will be issued for cancellation received after 1 February, 2019. 5.) All refunds due will only be issued by EFT after the Workshop. 6.) Any registrations received after 1 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 refund.

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