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
### 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.

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### 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

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**Introduction**

**Methods**

**Results**

**Discussion**

**References**

*Instructions: Text must be in Arial 10; the maximum length of 1 page must not be exceeded.*
WATERSHOP
NOVEL CLINICAL TRIAL METHODOLOGIES 2019
25 February 2019

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1 DAY WORKSHOP

Academia and Government  R 1,500.00
Industry, CRO’s, and others  R 5,000.00

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