

3rd Annual

Clinical Trials Forum

Identifying and countering the challenges associated with conducting clinical trials in South Africa

24, 25 and 26 June 2014
The Protea Wanderers Hotel
Illovo, Johannesburg

→ Your panel of expert speakers and panelists includes:

- > **Gavin Steel**, *Chief Director, Department of Health*
- > **Dr. Norbert Ndjeka**, *Director, Drug-Resistant TB, TB & HIV, Department of Health*
- > **Professor Bernd Rosenkranz**, *Head: Pharmacology, Stellenbosch University*
- > **Elize Botha**, *Associate Director: Clinical Operations, Parexel*
- > **Willem Kriel**, *Head: International Clinical Research Operations, Novartis*
- > **Dr. Roxana Rustomjee**, *Chief Specialist Scientist: TB Vaccines, Strategic Health Innovation Partnerships (SHIP), South African Medical Research Council*
- > **Leigh Howes**, *Clinical Research Operations Manager, Sanofi Aventis*
- > **Marzelle Haskins**, *Managing Director, Pharma Ethics*
- > **Mary-Ann Richardson**, *Managing Director, ACRO*
- > **Dr. Michelle Middle**, *Medical Advisor, Synexus Clinical Research*
- > **Frans van Wyk**, *Managing Director, Addclin Research*
- > **Dr. Essak Mitha**, *Principal Investigator, Newtown Clinical Research*
- > **Retha Britz**, *Founder, BCompliant*
- > **Diederik van Niekerk**, *Clinical Research Consultant*
- > **Dov Paluch**, *Director, Catalyst Solutions*
- > **Rob van den Bergh**, *Depot Manager, Logic Trials*

→ New and exciting topics for 2014 include:

- > Discussing the latest revision of the Declaration of Helsinki and how it improves the implementation of clinical trials
- > Looking at the new regulations for complimentary medicines and how this will affect clinical research
- > Novel licensure pathways for expeditious introduction of new tuberculosis vaccines: A discussion of the adaptive licensure concept
- > Pharmacokinetics of drugs in the paediatric patient population
- > Ensuring capacity and capability building of clinical trials through the use of government incentives: What's new?
- > Identifying business process improvement strategies at site level to invigorate SA clinical research
- > Establishing multi-centre clinical sites within government services
- > Looking at the challenges and solutions in maintaining controlled temperature environments for IMP from sponsor to depot to patient: A low risk approach

→ Why attend this event?

- > Sales pitch-free presentations which will allow you to go deeper into meaty subjects and benefit from honest group think
- > Carefully curated content and speakers highlighting new industry data to help you do your job better
- > Proactive dialogue and purposeful collaboration between all stakeholders involved in clinical trials
- > Hear clinical trial best practice case studies from leading pharmaceutical companies such as Novartis and Sanofi Aventis, CROs such as Parexel, Synexus, ACRO, Addclin Research and other industry practitioners
- > Online access to research materials that will serve as a helpful resource long after you have attended this conference

Pre-conference workshops

Voluntary Informed Consent for Clinical Research in South Africa: Ethical and Legal Perspectives

Facilitated by **Retha Britz**, *Founder, BCompliant*

&

Risk Based Quality Management in Clinical Trials

Facilitated by **Diederik van Niekerk**, *Clinical Research Consultant*

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Researched and
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Identifying and countering the challenges associated with clinical research

Dear Clinical Research Professional

Being at the forefront of drug development and being innovative during the process are important issues that are on clinical research professionals' minds. As clinical trials continue to be an essential part of developing medical treatments, executives in this field are pressed to find innovative solutions to recruit patients, meet regulations and use the appropriate technology (among other things) to complete trials in a timely manner and avoid exceeding the designated budget.

The 3rd Annual Clinical Trials Forum presents the opportunity for you to network and build partnerships with peer level professionals, while learning new ideas and strategies that you can replicate within your own organisation, to build a best practices culture. In just 3 days, you will master new strategies and best practices on the execution of sound clinical trials within the established costs, quality and time constraints.

The objective of this independent platform is to give you the opportunity to improve ways to productively produce studies that will be successful and meet important project milestones.

If you are a clinical research novice or veteran; with a study sponsor, research site, or CRO; in a corporate, academic or other organisation; you will find that this is a coherent and comprehensive programme that focuses on your current needs for applicable information. Meet people from all sides of the table in an open, friendly and energetic environment and establish collaborative relationships with all stakeholders involved that will build the clinical research community!

I look forward to meeting you at this independent forum in June.

Kind regards



Busie Mhlanga-Mjimba
Senior Project Manager: Conferences
Institute for International Research

P.S. Don't miss the keynote address entitled "Where to from here? Game changers that can revolutionise clinical research in South Africa" by Gavin Steel, Chief Director, Department of Health covered on day two, 25 June 2014

Day one: 24 June 2014

Pre-conference seminar

➔ Workshop one: Voluntary Informed Consent for Clinical Research in South Africa: Ethical and Legal Perspectives

Facilitated by **Retha Britz**, *Founder, BCompliant*

What will be covered

- > Looking at the ethical and legal foundation of obtaining informed consent in clinical research in terms of the guidance documents and relevant legislation applicable in South Africa
- > Discussing Consent Language
- > Providing adequate information and comprehension assessments
- > Sharing insights on the completion of an Informed Consent Document
- > Highlighting the content of a site specific Informed Consent SOP

Key learning outcomes

- > Determine the informed consent process for clinical research from an ethical and legal perspective
- > Discuss the concept of being informed from an ethical and legal perspective
- > Identify the correct way of completing informed consent documents from an ethical and legal perspective

➔ Workshop two: Risk Based Quality Management in Clinical Trials

Facilitated by **Diederik van Niekerk**, *Clinical Research Consultant*

What will be covered

This workshop will focus on understanding of risk based approaches to quality management of clinical trials. It will further promote discussions among stakeholders on how to move towards a more systematic, prioritised, risk-based approach to quality management of clinical trials in order to support the principles of Good Clinical Practice and to complement existing quality practices, requirements and standards.

Key learning outcomes

- > Understanding of the development and back-ground of risk-based monitoring
- > Understanding and knowledge of the FDA guidance and requirements for risk-based monitoring
- > Drafting a Monitoring Plan based on a risk-based quality assurance approach
- > Evaluating a protocol and determining the risks that need to be identified and addressed as part of the risk-based QA approach
- > Understanding the role of Data Management in risk-based monitoring

Registration starts at 08h00. The first workshop will run from 08h30 to 12h00. The afternoon workshop will run from 13h00 to 16h30. There will be breaks for refreshments and lunch.

Day two: 25 June 2014

08h00 Registration and early morning refreshments

08h30 Chairman's welcome and opening remarks **Dr. E. Mitha**, *Principal Investigator, Newton Clinical Research*

Legislative updates and developments in conducting clinical trial studies

08h45 **Analysing the changing environment of pharmaceutical research and development**

The main theme of this keynote is the future of medicine and issues the clinical trial fraternity is likely to face in the medium term. This presentation will review some of today's big debates and predict how the next 5-20 years will be shaped.

- > Looking at the future demographic and economic trends due to the increasing burden of diseases such as CVD, hypertension, obesity and diabetes especially with ageing populations
- > Exploring the issues related to declining R&D productivity and the opportunities presented by emerging markets, for example, the E7 economies
- > Considering whether big pharma can change its blockbuster model which relies on specialty products, and specifically look at the implications for the R&D process, innovation and licensing

Dr. Michelle Middle, *Medical Advisor, Synexus Clinical Research*

09h30 **Where to from here? Game changers that can revolutionise clinical research in South Africa**

- > Understanding the MCC's vision and goals for clinical research: 2014 Update
- > What does the future hold for clinical research and how can we make the best of it?

Gavin Steel, *Chief Director, Department of Health*

10h15 **Mid-morning refreshments and networking**

10h45 **Discussing the latest revision of the Declaration of Helsinki and how it improves the implementation of clinical trials**

- > Outlining the substantive changes relative to the previous version of the Declaration of Helsinki
- > Looking at the significant improvements of the new version of the Declaration of Helsinki document over preceding versions in relation to:
 - adequate compensation and treatment for subjects who are harmed as a result of participating in the research
 - researchers monitoring their own trial risks on an on-going basis and mitigating those risks
 - the inclusion of patients that are considered vulnerable in trials
- > What are the problems expected to emanate from the new version and how can these be alleviated?

Retha Britz, *Founder, BCompliant*

11h30 **Pharmacokinetics of drugs in the paediatric patient population**

- > Are children little adults?
- > How do changes in body size and maturation of organ function affect drug disposition?
- > What is the rationale for dosing instructions in children?

Professor Bernd Rosenkranz, *Head: Pharmacology, Stellenbosch University*

12h15 **Lunch and networking**

KEYNOTE ADDRESS

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ated with conducting clinical trials in South Africa

13h15 **Novel licensure pathways for expeditious introduction of new tuberculosis vaccines: A discussion of the adaptive licensure concept**

This presentation will explore the possibility of expediting licensure by use of an “adaptive licensure” process, based on a risk/benefit assessment that is specific to regional needs informed by epidemiology. This may be appropriate for diseases such as TB, where high rates of morbidity, mortality, particularly in high disease burden countries, impose an urgent need for disease prevention. The discussion focused on two contexts: licensure within the South African regulatory environment e a high burden country where TB vaccine efficacy trials are on-going, and licensure by the United States FDA – a well-resourced regulatory agency where approval could facilitate global licensure of a novel TB vaccine.

Dr. Roxana Rustomjee, *Chief Specialist Scientist: TB Vaccines, Strategic Health Innovation Partnerships (SHIP), South African Medical Research Council*

14h00 **Looking at the new regulations for complimentary medicines and how this will affect clinical research**

- > Outlining the regulations for complimentary medicines and how they contribute to reduced approval timelines for clinical research
- > Discussing the risk-based approach to quality, safety and efficacy provided in the guidelines: What does this mean for clinical research?
- > Examining the role of the MCC with regard to the new regulations: What does the future of clinical trials look like?

Frans van Wyk, *Managing Director, Addclin Research*

14h45 **Mid-afternoon refreshments and networking**

15h15 **Ensuring capacity and capability building of clinical trials through the use of government incentives: What's new?**

- > Outlining the refinements to the research and development (R&D) incentive, contained in the Income Tax Act in relation to clinical research
- > Revisiting the applicability of tax incentives to clinical research and development in South Africa
- > Assessing the feasibility and effectiveness of using tax incentives to improve clinical outcomes: sharing best practice case studies and recommendations

Dov Paluch, *Director, Catalyst Solutions*

16h00 **Lessons learned from unsuccessful clinical trials**

Numerous clinical trials are conducted in South Africa, of which most will face many hurdles and obstacles. Sharing the lessons learned from failed trials is perhaps the most valuable lesson in ensuring more successful future trials across industry. Following this year's theme of identifying and countering the challenges associated with conducting clinical trials, our panellists will come together to share lessons learned.

Leigh Howes, *Clinical Research Operations Manager, Sanofi Aventis*

Willem Kriel, *Head: International Clinical Research Operations, Novartis*

Dr. Michelle Middle, *Medical Advisor, Synexus Clinical Research*

Elize Botha, *Associate Director Clinical Operations, Parexel*

16h45 **Chairman's closing remarks**

17h00 **Close of day two**

Day three: 26 June 2014

08h00 **Early morning refreshments**

08h30 **Chairman's welcome and opening remarks**

Clinical trials site management and delivery

08h45 **Establishing multi-centre clinical sites within Government services**

- > An overview of the Bedaquiline treatment access programme of the National TB Cluster in South Africa
- > Analysing the challenges of establishing clinical research sites in the context of limited Government resources
- > Discussing the role of partnership in improving performance and collaboration between sites

Dr. Norbert Ndjeka, *Director, Drug-Resistant TB, TB & HIV, Department of Health*

09h30 **Reinvigorating clinical trial audits to promote quality improvement for clinical studies**

- > Looking at the current inspection environment: findings and trends
 - What are the current challenges?
 - Highlighting the opportunities for future clinical trial audits
- > Achieving compliance in clinical research through implementing a risk-based auditing approach

Mary-Ann Richardson, *Managing Director, ACRO*

10h00 **Mid-morning refreshments and networking**

10h45 **Risk-based monitoring case study**

- > Discussing the basic principles of risk-based monitoring
- > What are the pros & cons one should expect in this approach to clinical studies?
- > Going forward

Elize Botha, *Associate Director Clinical Operations, Parexel*

11h30 **Looking at the challenges and solutions in maintaining controlled temperature environments for IMP from sponsor to depot to patient: A low risk approach**

- > The EU directive
- > The challenge
- > Local solution

Rob van den Bergh, *Depot Manager, Logic Trials*

12h15 **Identifying business process improvement strategies at site level to invigorate SA clinical research**

- > Identifying process ineffectiveness and looking at areas for improvement at site level in order to enhance decision making effectiveness and thus improve operational productivity
- > Uncovering opportunities for business process improvement that will save time and costs, maximise site performance and meet the changing demands of the project
- > Developing a robust business process structure that will withstand shocks and uncertainty, and help implement flexible solutions that meet your unique business needs

Diederik van Niekerk, *Clinical Research Consultant*

12h45 **Lunch and networking**

13h45 **Developing successful strategies for staff retention on clinical trial sites**

- > Analysing the impact of staff turnover on deadlines and how this affects the quality of data for the trial
- > Finding practical solutions to study team turn-over in order to avoid losing momentum and alienating loyal site staff from your clinical study
- > Preparing for the unavoidable – how do you prevent the suspension of activity at clinical sites as a result of loss of staff?

Willem Kriel, *Head: International Clinical Research Operations, Novartis*

14h30 **Examining the use of electronic submissions to ethics committees in order to drive efficiencies in clinical studies**

- > Discussing the challenges associated with submissions to ethics review committees
- > How can you change your business model and manage clinical trials with electronic submissions?
- > Sharing best practice case studies

Mazelle Haskins, *Managing Director, Pharma Ethics*

15h15 **Mid-afternoon refreshments and networking**

15h45 **Investigating the clinical studies environment in South Africa: Trends of sponsorship approvals and site attractiveness**

- > Why are fewer trials coming to SA?
- > Where have we gone wrong?
- > What can we do to attract more work?

Mary-Ann Richardson, *Managing Director, ACRO*

Dr. Essak Mitha, *Principal Investigator, Newtown Clinical Research*

Frans van Wyk, *Managing Director, Addclin Research*

Leigh Howes, *Clinical Research Operations Manager, Sanofi Aventis*

16h30 **Chairman's closing remarks**

16h45 **Close of conference**

PANEL DISCUSSION

CASE STUDY

CASE STUDY

CASE STUDY

PANEL DISCUSSION

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