Speaker Profiles

09:15 – 09:45 Innovative Study Design

Speaker: Catherine Lund

Catherine Lund has been in the clinical research industry since 1995. She trained as a neonatal ICU nurse and subsequently entered into the clinical research field as a research nurse prior to moving into a CRA position. She started her own monitoring consultancy in 1999, which evolved into a full service CRO in 2008.
She has assumed the position of Managing Director for OnQ Research ever since. She has been actively involved in the South African Clinical Research environment by assuming roles such as vice chair for the South African Chapter for ACRP, served on SACRA exco as well as heading up the writing division for SACRA in 2015.
She is passionate about innovative and transformative research. Additionally, she considers herself an amateur politician and social activist. On a personal level, she has one husband and four children and enjoys running and reading.

09:45 – 10:00 The CRA of the Future

Speaker: Elandré Kok - B.Sc. Hons (Pharmacology) (Pret)

Elandré is a CRA at PPD and brings with him prior knowledge of Regulatory Affairs and Start-up matters for clinical trials. He is monitoring as part of the Government and Public Health Services group and is predominantly involved in infectious disease research across a vast multitude of protocols from Phase 1 to 3 for both adult and paediatric populations. Being both a millennial and a big techie, he is passionate about the use of technological aids to streamline processes whilst

improving outputs and the quality of the work produced. In his own words “why not use it when it can help us save time and make our lives that much simpler”.

10:30 – 11:30 Building quality in the conduct of Clinical Trials

Speaker: Savi Chetty-Tulsee - B.Soc.Sc.(Nur), ND Pharm. Marketing, CCRA, (DMS) DipTrn.T., Registered Assessor and Facilitator, Registered Quality Assurance Professional

Managing Director and Business Owner: SCT Consulting CC Savi Chetty-Tulsee has over 22 years of clinical research experience and has worked as a clinical research consultant in industry for +19 years. She has worked in a wide range of therapeutic areas with a predominance in infectious diseases. She has a proven track record based on service excellence in clinical operations, quality assurance and training. She has served on the SACRA executive committee for 9 years over the period 2003-2012, including various sub-committees, interfaced with the Ministerial Task team in contributing to the policy of change for the South African Regulatory Authority and led the first SACRA conference in 2007.

11:30– 12:30 Gene Therapy

Speaker: Prof Michael S. Pepper - MBChB (Cape Town), PhD (Geneva), MD (Geneva), Privat Docent (Geneva)

Michael Pepper is Director of the Institute for Cellular and Molecular Medicine, Director of the SAMRC Extramural Unit for Stem Cell Research and Therapy, and a professor in the Department of Immunology in the Faculty of Health Sciences at the University of Pretoria (UP). He is also *professeur associé* in the Department of Genetic Medicine and Development in the Faculty of Medicine at the University of Geneva, Switzerland. Michael obtained his MBChB in 1982 from the Faculty of Medicine at the University of Cape Town, and moved to Geneva in 1986, where he obtained his PhD in 1990, MD in 1992 and Privat Docent in 1997. Michael returned to South Africa in July 2004. He has

worked extensively in the field of clinically-oriented (translational) molecular cell biology, and his current interests include stem cells and the human genome as well as the ethical, legal and social implications of work in these fields.

Presentation Highlights

09:45 – 10:00 The CRA of the Future

Speaker: Elandré Kok

In his presentation he will highlight key information with regards to the data driven nature of current monitoring strategies and how this allows quick adaptation to mitigate identified risks. There is a slight twist to his presentation that will remain a closely guarded secret until the time comes to present it.

10:30 – 11:30 Building quality in the conduct of Clinical Trials

Speaker: Savi Chetty-Tulsee

According to ICH-GCP E6 R2, the sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and date are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirements. (ICH-GCP E6 R2 5.1.1) Quality Control should be applied to each stage of data handling to ensure that all data are reliable and has been processed correctly. (ICH-GCP E6 R2 5.1.3). In the recent revision R2 to ICH-GCP E6, additional clarity on quality management was included within the guidelines. Sponsors are to look at developing methods that control and assure quality in a trial proportionate to risks inherent in the trial and the importance of the data collected. The proposed talk will briefly cover concepts of quality control, quality assurance, audits and inspections, strategies for Investigator oversight and building quality in conducting clinical trials.

11:30 – 12:30 Gene Therapy

Speaker: Prof Michael S. Pepper

Imagine a world in which disease management is highly personalized. Drug treatments would be specific to the individual concerned, taking into account genetic background and environmental factors. Therapies would be effective, tailored to the individual's needs, with few or no side effects. Given that at present many of our therapies are based on a one-size-fits-all approach, which clearly has its limitations, personalized medicine is an important ideal to pursue.

Hematopoietic stem cell transplantation (HSCT) is universally applied and has been performed successfully for several decades; several new cell and gene based therapies have recently been introduced into the clinical arena and many more are on the horizon. Impressive results have been obtained with CART cells and haematological malignancies, and with gene therapy for genetic disorders (haemophilia, PID). Gene therapy for diseases that are highly prevalent on the African continent are imminent: infectious diseases (HIV) and haemoglobinopathies (sickle cell disease and

thalassemia) being good examples. An exciting future awaits us as these innovative therapies come to the fore.