

Dr. As 'ad Bhorat. (MB BCh, MCFP, DA, FCFP, MMed Sports Medicine – University of the Witwatersrand)

I am currently working as a Family Physician in private Practice in Soweto and as a Principal Investigator at the Soweto Clinical Trials Centre. I was appointed to the MCC Clinical Trial Committee as an Independent Reviewer in 2008 and bring this perspective with me to SACRA.

It is an exciting time for Clinical Trials in this country. While there are challenges for all of us, it is clear that we have the people and skills in this country to take clinical trials to a new level. Having been given a solid foundation by the 2009 Exco, SACRA must use this opportunity to grow further and take its rightful place as a world leader in its field. SACRA has the potential to contribute significantly to a vibrant and sustainable future for clinical trials in SA with huge benefits for this country and its people. It would be an honour and a privilege to be part of SACRA as it undertakes this journey.

Esmarie Venier. Nursing Diploma (General, Midwifery, Psychiatry & Community Nursing) & BA (Cur) Administration & Education

I am currently the Managing Director of Call Quick South Africa

My introduction to clinical trials in South Africa was as a Clinical Trial Study Site Coordinator for Dr Annemarie Potgieter and Dr Philip von Brandis-Martini, both psychiatrists in private practice on fifteen psychiatric clinical trials between 1999 and 2005. This exposure ensured that I obtained extensive clinical trial experience within the parameters of good clinical practice, ethics and MCC processes as well as complete project management of all trials at site level.

Since 2001 I have been the Managing Director of my own company - CallQuick which is a centralised patient recruitment business for the South African clinical trial industry and global multi-national pharmaceuticals. Our main objective is to be the voice of the patient within the context of voluntariness, observance of vulnerability and enhancing opportunity of being enrolled into a clinical trial.

During 2009 we have developed two further supportive strategies to grow and force focus on patient recruitment in South Africa. Firstly, a secure online patient and investigator registry and secondly, a patient recruitment conferencing platform. Both will be launched on 19 May 2010. It would indeed be an honour to be part of SACRA's continuous growth from strength to strength as the voice of industry. Maybe, I could be the voice of our population and by implication, our patients. Without whom, no clinical trials could happen.

Dr. Essack Mitha. (MB BCh)

Qualified as a medical doctor at University of KZN in 1998. Works as a full time principal investigator since 2002, in Newtown, Johannesburg.

Published 2 scientific letters in the SAMJ. Currently working towards a masters degree in medical science.

Assisted with the setup and training of new investigators and staff in Synapta Clinical Research, in Durban.

Served as a SACRA Exco member in 2008-2009. Assisted with increasing exposure of SACRA to investigators and sites, and drew up SOP guidelines for SACRA.

Presented an SOP workshop at the last SACRA Conference.

My plans are to draw up policy documents, which would assist to standardise the clinical trial industry in SA.

Eugene Liebenberg. B.Med.Sc (Hons) Pharmacology.

Previous experience: Just over 20 years in Community pharmacy

Clinical research experience:

1997 to 1999 Quintiles - CRA

1999 to 2001 Bristol-Myers Squibb - Contract CRA

2001 to 2007 Bristol-Myers Squibb – Clinical Site Monitor Manager

2007 to current PPD - Clinical Manager

Currently involved with training, coaching and performance management of a team of CRA's on procedural documents and other processes relating to clinical trials facilitating their professional development. Eugene has keen interest in developing standards on procedures in industry to improve the quality of clinical trials in South Africa. SACRA should be involved in creating a unified approach to ensure quality data is being collected at all sites in South Africa by creating standards on issues like dispensing in clinical trials, source documentation, informed consent processes et cetera.

Joe Voogt

Currently employed by CLintec **International Ltd** (CRO with Headquarters in Glasgow) as a Senior CRA. Joe has been contracted to MSD Merck for the last 18 months as home based Cape Town CRA. In her current role she mainly acts as site manager for Cape Town sites and is involved in a number of therapeutic areas.

Prior to joining Clintec, Joe was employed by ACRO for 13 months and prior to that at AstraZeneca Pharmaceuticals for a period of 22 months. Joe was employed at a research site (Tread Research) as a study coordinator before moving over to Astra Zeneca as CRA. There she gained valuable hands on training from a site perspective.

Joe also worked at PathCare Clinical Trails where she was employed for almost 9 years prior to joining Tread Research. She started off as phlebotomist within the company in 1997 and moved over the Clinical Trial Department 2001 to broaden her horizon and to enter the challenging environment of Clinical Trails. There she gained valuable experience while working setting up the pathology side of protocols. She started off as study coordinator in the department, she was promoted to Assistant Project Manager (APM) and then to Project Manager (PM). I see this as an opportunity to give back to the industry and organisation that over the last couple of years have done so much for the clinical trials in South Africa

Karen Micklethwaite (B.Soc.Sc Nursing)

Managing Director of InGonoGo Co-ordinators

Karen comes from a nursing background.

From 1989 she has worked as a contractor and full time Study Co-coordinator and Monitor.

Currently she trains Sites and individuals on GCP, running a course called "Clinical trial GCP Co-ordination in Practice".

Karen is also a Site facilitator and helps in setting up sites. She is also a placement and recruiting agent.

She has worked on projects in a wide spectrum of various disease areas from Phase 1 to 4. She does registry, surveys, and in-house studies.

She sees intends to add value with her first hand experience and expertise with Sites in developing their capacity.

She would also be a voice for the Sites.

Prof Lesley Burgess. (MB BCh, MMed, PhD, Dip International Research Ethics)

Lesley runs 2 clinical trial units in the Western Cape, TREAD Research CC (Cardiology Unit, Tygerberg Hospital) and Paarl Research Unit. In addition, she works as a consultant for the Wits Donald Gordon Clinical Trials Unit, setting up clinical trial units and also developing clinical trial training courses. She has been involved in clinical trials for 17 years and has run more than 300 trials to date.

She has been on the SACRA Exco for the last 2 years, is an independent reviewer for the MCC, serves on the GCP accreditation subcommittee and has served on the Stellenbosch Ethics Committee for the last 6 years. If re-elected, she intends to continue her drive to encourage more investigators to join SACRA and to work towards resolving the MCC issues within the country.

Linda Roach. (B.Sc Pharmacology; M.Sc Forensic Science, Strathclyde)

Linda Roach, currently Country Manager, Global Clinical Operations, Janssen-Cilag and Industry member of SACRA. I have worked in the South African clinical research industry for more than 20 years except for a 3 year period from 2004 – 2006 when I worked as a Clinical Research Manager in the UK. Starting my CR career as a CRA for Sandoz products at a time when GCP was only beginning to become entrenched in our business I have seen clinical trials evolve into the high quality studies we run today.

Currently I manage a clinical research group of 13 individuals including CRA's, CTA's, contractors and also have one CRA based outside of our borders in Uganda. I have been a member of SACRA since its inception but until this point have not taken any active role in its management. I would like to see SACRA move on to the next stage and become 'recognized' as the 'professional' body, representative of our growing industry and one which engages with other interested groups to increase the capacity and improve efficiency of trials in South Africa so we become a 1st line destination for placing trials. If elected, I would bring my expertise as a CR professional, enthusiasm and a will to complete anything I start to the EXCO

Dr. Luthando Adams. (MBChB; CPI)

Medical Executive/Deputy Country Manager, AddClin Research (Pty) Ltd / Synexus Clinical Research SA (Pty) Ltd
I qualified in Medicine (MBChB) at the University of Cape Town. I obtained the Certified Physician Investigator (CPI) qualification of the American Academy of Pharmaceutical Physicians and Investigator in 2008. I am also a Member of the American College of Clinical Pharmacology (MACCP). I am currently studying the MBA degree at the University Of Cape Town Graduate School Of Business. I have been an investigator in more than 200 clinical trials and Sponsor Study Director of more than 10 clinical trials. I previously worked at Guy's Drug Research Unit, Quintiles in London,UK; PPD in Cambridge,UK; Genzyme in Cambridge,UK; PAREXEL SA in Port Elizabeth.
I have broad therapeutic, clinical trial and business administration experience gained in the UK, US and South Africa which will be of immense benefit SACRA. I also have extensive local and overseas contacts which will help advance SACRA's cause.

Dr. Lynn Katsoulis. (PhD Pharmacology)

Lynn holds a PhD in pharmacology and has had about 14 years of experience conducting research, of which 7 years have been in clinical research. Lynn has been on the SACRA Exco for two years in the role of either vice chairperson or chairperson, and is the outgoing chairperson for 2009.

If re-elected, she intends to encourage more SACRA members to work in teams all working towards the standardization of policies within the industry, and would like to encourage the formation of sister organizations throughout Africa. Tasks that she would like SACRA to work towards are for SACRA to start endorsing GCP courses, increasing the amount of data and tools available to site coordinators and investigators (for example the drafting of SOP templates for the sites to use) and to increase the involvement of site staff within the organization.

She is willing to continue collecting MCC tracking information to continue lobbying the MCC to improve timelines, and to continue making the tracking results available to all members to help the attraction of trials to South Africa.

She is also keen to see SACRA step up its role and find a place as a National body that fully represents the needs of all Clinical research professionals.

Lynne Inglis - ND Med Tech (Chem Path) and ND Micro

I am currently Ampath Clinical Trial Manager. I am an enthusiastic, efficient and helpful Medical Technologist qualified in Chemical Pathology, and registered with the HPCSA with extremely good attention to detail. I hold an addition technical qualification in Microbiology and have almost 40 years experience in pathology, mostly as Laboratory Manager. I also have one year quality control experience in pharmaceutical production. In addition, I hold an International Internal Auditor's Certificate and attended additional training on handling FDA audits. I was instrumental in implementing Ampath's quality system for accreditation compliance and have lectured at numerous Quality Seminars on quality issues and provided quality and accreditation training to laboratories. During my 10 years experience as Quality Manager in Ampath's QA department, where I was involved with Clinical Trial audits, I subsequently became the best equipped person to head up the Ampath Clinical Trial department and I took over this position in October 2000. I have had SANAS GLP and GCLP training and sat on the technical committee for GCLP. The laboratory plays an extremely important role in data collected during a clinical trial and if I am elected onto the SACRA Exco, I can provide useful information to enable suitable sample collection and transportation of these samples to laboratories to ensure reliable reporting of laboratory data. I can, and would be willing to, provide training to SACRA members on laboratory procedures, plus I have extensive experience in preparing and assisting with audits, which can be of valuable assistance to SACRA members and the industry as a whole.

Mark Shardelow BA Maj (Theol), BAA, AEA

My name is Mark Shardelow; I started working at AddClin Research in 2006 as a project manager. Shortly after that I was promoted to Chief Operation Officer.

AddClin Research is a phase 1 unit which has carried out BE/BA trials mainly but is presently expanding its wings into "First in man."

I have a BA (Theol) degree and numerous additional counseling qualifications but was drawn to emergency medicine where I completed paramedical training and ended up as a lecturer in anatomy and physiology. A friend introduced me to the world of clinical trials - New challenges and horizons, hence the move.

Mary-Anne Richardson. (BA.HSS. Health Science Ethics and Law)

I have been involved in the administrative and regulatory aspects of medical research and drug development for over 9 years, and have held several senior managerial posts with large international CROs prior to my current position of Managing Director at ACRO, a full-service, locally owned CRO.

In the course of my career, I have developed an extensive network of contacts throughout the pharmaceutical industry, in South Africa, the southern African region, and abroad; established cordial and productive relationships with regulatory agencies and other overseeing authorities; and maintained active links with researchers in industry, government institutions, and the academic community.

I have obtained accreditation as facilitator and assessor from the South African Qualification Authority's Education and Training Development Practice (ETDP) Sector Education and Training Authority. I have been fortunate to have been given the opportunity to deliver presentations on Good Clinical Practice, clinical research, and the role of CROs at venues in South Africa, Malawi, and the UK, and have delivered postgraduate lectures on clinical trials at the University of the Witwatersrand.

I have assisted in the development and delivery of the internationally accredited CRA training course at ACRO and am a member of the CRA Unit Standards working group and the NHREC's GCP-sub committee.

I believe that I can add value to SACRA by building on the projects identified by the 2009 EXCO, particularly in the areas where I am already active, namely the GCP sub-committee and CRA Unit Standards working group.

I am a strong supporter of networking and information sharing, and would like to see the SACRA membership expand to include amongst others, the growing clinical biotech industry in South Africa - an area I'd be happy to develop. I'd bring with me my enthusiasm, a positive can-do attitude and a commitment to the members that SACRA will continue to strive to meet their needs.

Nicky Sulzer (B.Med.Sc. (Hons), Biokinetics, M.Sc.Med Exercise Science)

I am currently employed by two clinical trial sites, Paarl Research Centre and TREAD Research in Tygerberg Hospital. I hold an MSc (Med) and have been working in the clinical trial industry for 5 years.

I was fortunate enough to be nominated to the 2009 SACRA Exco and I learnt a tremendous amount from my participation in the Committee. I still feel that site membership in SACRA needs to be encouraged and while some progress was made towards achieving this goal over the past year, I would like to dedicate further time to this if elected next year.

Additionally, I feel that continuity is crucial in a Committee such as SACRA accomplishing its goals and I would like to have a further opportunity on the Exco now that I am familiar with its workings. There are a number of exciting changes planned for SACRA for the next few years and I would sincerely like to be part of the team that makes those plans a reality.

Norbert Tamm Dip. MSc

I currently work at PPD as Principal CRA. Previously, I worked with the Reproductive Health and Research Unit (RHRU) in Soweto as Project Manager and Internal Auditor, setting up study sites for an international HIV study. Prior to that, I worked in the United Kingdom for Imperial College as a Senior Research Nurse and subsequent Study Coordinator/Project Manager. I conducted a high number of (qualitative & quantitative) international commercial and government-related studies. During that time I also completed my Masters Degree in Research and was able to present my dissertation topic at the World AIDS Conference in Milan in 2003. Before I engaged in the field of clinical research, I worked as a general registered nurse in the field of palliative care and AIDS/HIV in-and outpatient care at St Mary's Hospital London for many years.

Throughout my career, I have been exposed to clinical research from a variety of angles and through differing professional roles and was able to obtain a vast level of experience. This has also helped me to gain a very good understanding about interaction amongst various professionals, comprehending the various perceptions as well as taking part in breaking down barriers between general health care and clinical research groups. I would therefore be able to contribute a variety of skills and grounded experience in the field of clinical research.

Overall, I feel strongly that sharing of knowledge and experience across various professional groups within the field of clinical research can assist in breaking down barriers; it can increase respect, understanding and interest amongst professionals, as well as identifying gaps of knowledge and further areas of interest to explore. In my view, SACRA has a unique role in bringing different groups of professionals together, encouraging exchange of information as well as promoting a respectful, constructive and effective relationship amongst the various groups involved in clinical research. Furthermore SACRA has the opportunity to act as a respected body to initiate and promote discussion on newly emerging areas of clinical research.

Retha Britz. (B.Sc Nutrition and Physiology; M.Sc. Physiology)

Independent consultant and GCP Provider with BCompliant

I've been involved in clinical research for the past 10 years in which I held several positions such as: CRA, Snr CRA, Snr International Clinical Operations Study Manager, Consultant, CRA/CTA Trainer, Mentor, Independent GCP Compliance Auditor, Independent Ethical Compliance Site Monitor/Auditor, GCP Training Facilitator and Regional Quality Assurance Manager for Africa and the Middle-East.

I am passionate about life and take challenges seriously... If I'm elected on the SACRA Exco, this challenge will allow me to serve and to give more of myself to the Pharmaceutical Industry in South Africa.

As we need more Investigators and site staff to become aware of SACRA and join the Association, I would be happy to help promoting SACRA actively under this group.

Also it would be to the benefit of the Pharmaceutical Industry and clinical research as a whole in South Africa if we can increase the overall GCP compliance in research together by finding the most effective ways and reach consensus on certain research activities for example where CRA's and Companies work totally different from each other on similar aspects. This, as well as the implementation of the Unit Standards to accredit CRA's will help to improve the quality of research we conduct in this country.

I believe that SACRA can play a guiding role in this regard, as well as getting more clinical trials to be conducted in South Africa since it is one meeting point for everybody involved in clinical research in South Africa where consensus can be reached on certain activities.

Robert Voogt ND Medical technology (Clin Path), Certificate Project management (US Business School)

Employed by PathCare (Dr's Dietrich Voigt Mia and Partners)

Position: Administrative manager Pathcare Clinical Trials.

Work experience:

Joined Pathcare in 1986

Appointed as Head of Laboratory – Durbanville laboratory - 1995

Appointed as Administrative manager PathCare Clinical Trials - 2000

Primary functions include general management, compliance to ICH GCP, ISO 15189 and IATA, ensuring we meet both technical and operational requirements set by our clients, development and planning of the Clinical Trial department within the larger Pathcare group.

I have attended courses on GCP, GLP, IATA and Quality management. I further have an interest in IT systems validation, 21 CFR part 11 compliance and the development of systems to compliment our services to the industry.

I believe SACRA is the vehicle to coordinate and address issues in the clinical trial industry, and although labs form a small part of it, I am willing to volunteer my services to SACRA.

Savi Chetty- Tulsee B.Soc.Sc.(Nur), ND Pharm. Marketing, CCRA, (DMS) DipTrn.T. Registered Assessor & Facilitator

Current Status: Managing Director SCT Consulting, Managing Director AGCP, Vice Chair SACRA, Chair CRA Unit Standards Working Group, Vice Chair GCP Sub Committee of the NHREC

Savi Chetty-Tulsee has over 12 years of clinical research experience and is well respected and recognized as a GCP trainer in industry.

Savi has a proven track record in her volunteer services to the clinical research industry since 2003 having served on the SACRA executive committee, 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. If re-elected, Savi will continue to contribute her driven, dynamic attitude and experienced leadership in the process of change and evolution envisaged for SACRA.

Tebogo Sebata. (B.Sc (Univ. of the North), B.Sc Honours, M.Sc (MEDUNSA)

Work Experience:

01 Dec 2005 – Present: Pfizer Laboratories, Clinical Study Manager (3.6 yrs)

01 December 2003 – 30 Nov 2005: Pfizer Laboratories, Senior Clinical Research Associate (2 Yrs)

01 Aug 2001 – 30 Nov. 2003: Pfizer Laboratories, Clinical Research Associate (2. 3 Yrs)

01 Oct. 2000 – 31 Jul 2001: Cro-Medical (CRO), Business Development Assistant (9 Months)

01 Jun 1999 – Sep 2000: Dept of Health (National Center for Occupational Health), Medical Natural Scientist (1.3Yrs)

- Managed and monitored Studies both locally and the rest of Africa, which involves learning about International requirements/guidelines in research on humans.
- Managed and monitored studies in the following therapeutic areas:-
Infectious Diseases, Female Health, Cardiovascular, Pain, CNS, Metabolic Disorders
- Involved in GCP training of doctors who do not have any clinical trial experience since 2002 (7yrs)
- Involved in company strategic input and direction.

I would like to be part of the SACRA team that will build the environment that we operate in to a level where there is synergy among all stakeholders (Pharmaceutical, regulatory, investigators etc.) by engaging everyone involved.

Teresa Scanes. (B.Med.Sc (Hons) Analytical Pharmacology)

Independent Contractor with Clinical Monitoring Services

During my 8 years of involvement in the Clinical Research industry in South Africa, I have worked as a CTA and CRA. I established Clinical Monitoring Services when the opportunity arose to work as an independent contractor and to mentor junior staff who wished to gain some experience as CRAs.

I have a B.Med.Sc (Hons) degree in Analytical Pharmacology from the University of the Orange Free State. Apart from my time in clinical research, I have 7 years in an analytical laboratory, at the FARMOVS-Parexel BioAnalytical Services Division. This combination of analytical and clinical work has given me a great understanding of the clinical research process as a whole. Having already served on the SACRA Exco for 2 years, I believe that I have the current understanding of the potential role that SACRA can play within the industry. I have an extremely positive outlook on the potential for this industry in South Africa and indeed Africa. I would like to be a contributing player in increasing the awareness of the very important role that SACRA can play on this continent.

Willem Kriel. (BA (Hons) Indus Psych & Project Management)

Clinical Research Manager, Regional Clinical Operations, Bristol-Myers Squibb.

My career started in the Pharmaceutical Industry at a CRO (PAREXEL), after a period of 4 years as Human Resources Practitioner. At the CRO, I was introduced to Phase I/II clinical studies as a CRA/Project Manager. After 2 years, I joined Janssen-Cilag as a CRA and was promoted to Global Trial Manager 3 years later. During this period, I was responsible for the management of clinical trials in various countries, including the USA, which was a great opportunity to experience clinical trial activities and challenges across the globe. I was then promoted to Country Manager (South Africa) for the same pharmaceutical company, taking care of clinical trial business in South- and Sub Saharan Africa. In June 2006, I was offered the position of Director: Business Development at PAREXEL International and I joined Bristol-Myers Squibb 18 months later.

I believe I have experience in both the CRO environment as well as pharmaceutical companies to contribute to SACRA Exco. The current Exco did a great job as far as the various projects are concerned, which make me excited about the progress this organization has made. As a proud South African, I do believe that our country, as well as the continent, are playing a vital role in conducting ethical sound and quality clinical trials and will be more than happy to build on what we currently have. I fully support the current Chair's vision regarding the future of SACRA, i.e. rise up to a higher level and have huge impact on Clinical Trials in South Africa. Let's do it!

Zelna Vermooten. (B.Soc.Sc Nursing)

I am a Registered Nurse, studied B.Soc.Sc (nursing) at UOFS and qualified in 1990. I worked in Provincial and Private Hospitals until 1999 (permanent and part time), then moved out to Private Practices. I am currently working as Practice Manager and Study Coordinator at a Physician's practice. We have been conducting clinical trails for 8 years, doing both in and out of hospital studies, as well as Registries. I hope to bring some practice experience and knowledge on Site coordination and what sort of capacity needs to be developed to make good Site coordinators.