CURRICULUM VITAE FOR: Siza Mphele

NAME:	Siza Mphele
ADDRESS:	**9 Ponderosa, 102 Reddersburg Street, Wierdapark, 0157**
Contact:	**siza@ltclinicalresearch.co.za / +27 83 978 7077**
EDUCATION:	National Diploma: Clinical Technology (Specializing in Assisted Reproduction) Bachelor of Technology: Clinical Technology (Specializing in Assisted Reproduction) Master's Degree in Technology: Pharmaceutical Sciences
MAIN EXPERIENCE:	Clinical Technologist in Assisted Reproduction (8 years), Clinical Research (12 years)
TRAINING / CERTIFICATIONS / MEMBERSHIPS:	Member of South African National Research Ethics Committee – GCP Sub Committee from Jul 2009 to 2016 Member of South African Clinical Research Association from 2012 to Present
LANGUAGES:	Zulu, South Sotho, Xhosa, Setswana, North Sotho, English, Afrikaans
CAREER HISTORY	
DATE (from Jul 2014 - to)	**POSITION/EMPLOYER/LOCATION**
Nov 2015 to June 2016	Lead Clinical Research Associate/ARIANNE/S. Africa Responsibilities: • Oversee day-to-day monitoring activities on a project level to ensure the reporting of high quality data and timely query resolution, including flow of documents and information to and from sites and/or external vendors (CROs, CRAs). • Manage the clinical monitoring activities of the study, and assures site compliance with study protocols and GCP. • Oversee and act as mentor for less senior members of the Clinical Team. • Implement and monitor clinical trials in all phases of drug development.

	• Conduct pre-study, initiation, routine, and closeout visits and report findings in a site visit report. • May conduct quality assurance activities to assure the compliance of company SOPs, FDA and ICH guidelines of contract research organizations, study coordinators, investigators, and independent consultants. • Assist in regulatory filings with local agencies. • Adhere to company SOPs, FDA regulations and ICH guidelines. • Track clinical data, regulatory documents, patient enrollment, and data resolutions to assure the timely completion of clinical studies. • Communicate with sites, clinical vendors, and others within the company, both in and outside the department. • Act as primary contact to sites and local regulatory agencies. • Primary contact with MCC and local ethics committees. • Review and resolve discrepancies in clinical data at clinical sites and central laboratories via query process. • Provide technical and administrative assistance to the department. • Identify and assist in the selection and implementation of clinical sites. • Select, design and implement the data collection method and tools with vendors. • Assist in the creation of informed consents, case report forms, instruction manuals, newsletter, and monitoring and tracking tools. • Oversee delivery and shipment of clinical trial supplies and ensure accounting of usage in clinical studies. • Perform clinical finance duties (site payments, CRO payments etc.) • Perform other duties as required. **General Responsibilities:** • Operate to the highest ethical and moral standards. • Comply with ARIANNE policies and procedures. • Adhere to quality standards set by regulations, and ARIANNE policies, procedures and mission. • Communicate effectively with supervisors, colleagues and subordinates. Be committed to team effort and be

	willing to assist in unrelated job areas when called upon. • Provide administrative leadership for us and provide knowledge-based expertise in related areas that can be applied to meeting the strategic goals. • Travel as needed.
Oct 2015 - Current	Managing Director and Clinical Research Manager /LT CLINICAL RESEARCH/ Responsibilities: Oversee day to day running of the company Human resource for the company Develop and implement company strategy Assist with business development and marketing Clinical Trial Responsibilities: • Conduct Study Feasibilities on behalf of the sponsor; • Select, and recruit investigators; • Conduct Qualification visits (PSSV); • Conduct site initiation visits • Conduct routine Study Monitoring Visits; • Site Management; • Compile and submit applications for Regulatory and Ethics approval; • Write clinical trial monitoring reports; • Oversee research projects; • Organize meetings with the client • Train and supervise junior staff Leadership Responsibilities: • Communicate project plan and timelines to Monitoring team • Participate in the development of CRFs and Informed Consent. • Monitor and track study implementation and progress • Organise internal communication flow • Act as liaison between clinical monitoring and other functional departments (external) • Take concepts from idea to implementation • Identify problems that interfere with study progress, implement strategies to resolve issues in consultation with Sponsor • Provide leadership to Monitoring team and coordinate monitoring activities • Mentor Monitoring team and conduct co-monitoring /

	training visits • Act as primary client contact for specific monitoring related activities. • Responsible for the development of study specific monitoring plan, monitoring conventions tracking forms and other study related documents
Dec 2008 – Sep 2015	Managing Director and Project Manager /LogicTrials-SA/ Responsibilities: • Oversee day to day running of the company • Human resource for the company Clinical Trial Responsibilities: • Conduct Study Feasibilities on behalf of the sponsor; • Select, and recruit investigators; • Conduct Qualification visits (PSSV); • Conduct site initiation visits • Conduct routine Study Monitoring Visits; • Site Management; • Compile and submit applications for Regulatory and Ethics approval; • Write clinical trial monitoring reports; • Oversee research projects; • Organize meetings with the client • Train and supervise junior staff Leadership Responsibilities: • Communicate project plan and timelines to Monitoring team • Participate in the development of CRFs and Informed Consent. • Monitor and track study implementation and progress • Organise internal communication flow • Act as liaison between clinical monitoring and other functional departments (external) • Take concepts from idea to implementation • Identify problems that interfere with study progress, implement strategies to resolve issues in consultation with Sponsor • Provide leadership to Monitoring team and coordinate monitoring activities • Mentor Monitoring team and conduct co-monitoring / training visits • Act as primary client contact for specific monitoring

	related activities. • Responsible for the development of study specific monitoring plan, monitoring conventions tracking forms and other study related documents
Mar 2007 – Nov 2008	Project Leader /Clindev-Holisizwe Medical/ Responsibilities: • Conduct Study Feasibilities on behalf of the sponsor; • Select, and recruit investigators; • Conduct Qualification visits (PSSV); • Conduct site initiation visits • Conduct routine Study Monitoring Visits; • Site Management; • Compile and submit applications for Regulatory and Ethics approval; • Write clinical trial monitoring reports; • Oversee research projects; • Organize meetings with the client • Train and supervise junior staff Leadership Responsibilities: • Communicate project plan and timelines to Monitoring team • Participate in the development of CRFs and Informed Consent. • Monitor and track study implementation and progress • Organise internal communication flow • Act as liaison between clinical monitoring and other functional departments (external) • Take concepts from idea to implementation • Identify problems that interfere with study progress, implement strategies to resolve issues in consultation with Project Leader • Provide leadership to Monitoring team and coordinate monitoring activities • Mentor Monitoring team and conduct co-monitoring / training visits • Act as primary client contact for specific monitoring related activities. • Responsible for the development of study specific monitoring plan, monitoring conventions tracking forms and other study related documents
Jul 2006 – Feb 2007	Clinical Research Associate II /Kendle-SA / Responsibilities:

	• Complete project activities associated with monitoring functions of Phase I-IV clinical research studies while developing an understanding of the drug development process, Good Clinical Practices and relevant regulations. • Provide clinical and technical support for CRA I and administrative staff. • Perform management of study site activities to ensure the integrity of clinical data, in adherence to all applicable regulatory guidelines and Standard Operating Procedures and Project Specific Operating Procedures • Assume the role of a lead CRA on projects by providing direction and guidance to the project team, coordinating all monitoring activities and communicating the status of these activities to the study Project Leader. • Travel to study sites.
Mar 2005 – June 2006	Clinical Research Associate /Clindev Holisizwe / Responsibilities: • Conduct Study Feasibilities on behalf of the sponsor; • Select, and recruit investigators; • Conduct Qualification visits (PSSV); • Conduct site initiation visits • Conduct routine Study Monitoring Visits; • Site Management; • Compile and submit applications for Regulatory and Ethics approval; • Write clinical trial monitoring reports; • Train and supervise junior staff
Mar 2004 – Feb 2005	Clinical Research Administrator /Clindev-Holisizwe/ Responsibilities: • Conduct Study Feasibilities on behalf of the sponsor; • Conduct Qualification visits (PSSV); • Conduct site initiation visits • Assist in conducting routine Study Monitoring Visits; • Assist in compilation and submitting applications for Regulatory and Ethics approval; • Write clinical trial monitoring reports; • Organize meetings with the client

Apr 2001 – Feb 2004	Senior Clinical Technologist /Pretoria Academic Hospital/ Responsibilities: • Laboratory experience • Planning & organising the daily laboratory routine • Performing assisted reproductive techniques (handling, culturing and cryopreservation of gametes, embryos and blastocysts) • Implementing a Quality Assurance Programme • Supervising & Training junior lab staff • Daily liaison with clients, doctors and staff • Patient statistics and record keeping • Procurement & manage established budgets (cost containment)
Apr 1999 – Mar 2001	Clinical Technologist /Pretoria Academic Hospital / Responsibilities: • Laboratory experience • Planning & organising the daily laboratory routine • Performing assisted reproductive techniques (handling, culturing and cryopreservation of gametes, embryos and blastocysts) • Implementing a Quality Assurance Programme • Daily liaison with clients, doctors and staff
1996 - Mar 1999	Student Clinical Technologist /Pretoria Academic Hospital/ Responsibilities: • Laboratory experience • Planning & organising the daily laboratory routine • Performing assisted reproductive techniques (handling, culturing and cryopreservation of gametes and embryos) • Daily liaison with clients, doctors and staff

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LIST OF CLINICAL TRIAL PARTICIPATION

NAME:	Siza Mphele
PARTICIPATION IN CLINICAL TRIALS	
DATE	**TRIAL INFORMATION**
Nov 2015 – Jun 2016	Phase II trial in metastatic breast cancer
Sep 2015 - Ongoing	Epidemiology Study - Co-infection between helminths and malaria
Sep 2015 - Ongoing	Epidemiology Study – HIV and Pneumococcal Surveillance
Sep 2015 - Ongoing	Epidemiology Study - Rotavirus
Jun – Nov 2014	Phase III trial in Flu
Jul 2014 – Mar 2015	Bioavailability / Bioequivalence Trial in nutrition
Apr 2013 - Ongoing	Phase III trial in MDR TB
Jan 2009 – Sep 2012	Phase III trial in medical devices in venous leg ulcers
Feb 2008 – Jun 2010	Phase III trial in benign prostatic hyperplasia
Jun 2007 – Feb 2008	Phase III trial in Rotavirus vaccine
Jan - Dec 2005	Phase II trial in complicated skin and skin structure infections
Jan – Dec 2005	Phase III trial in Hospital Acquired Pneumonia – focusing on MRSA infections
Aug – Dec 2005	Phase III endometriosis
Feb 2004 – Sep 2015	Epidemiology and Treatment Trial - HIV and co-infections
Feb 2004 – Apr 2008	Phase IV trial in HIV treatment

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OTHER TRAINING AND PUBLICATIONS

PUBLICATIONS

Co-Authored

TITLE	PUBLISHED
In vitro effect of medicinal plants used to treat erectile dysfunction on smooth muscle relaxation and human sperm.	Journal of ethnopharmacology. 21 April 2006, Vol. 105 issue 1-2: 84-88.
The Utilization of Monitoring Benchmarks for Site Performance Evaluation in Project Phidisa.	Applied Clinical Trials, 01 Jul 2008

OTHER RELEVANT INFORMATION (eg. Presentations, training courses given)

DATE	DETAIL
July 2004	The Ethical Review of Clinical Research – Poster presentation at the 1st Annual Phidisa Conference in Richards Bay
July 2004	Racial Composition of Institutional Review Boards (IRBs)/ Ethics Committees (ECs) in South Africa: The Phidisa Experience - Poster presentation at the 1st Annual Phidisa Conference in Richards Bay
July 2004	Clinical Trials Monitoring and Adverse Event Reporting on the PHIDISA Project - Poster presentation at the 1st Annual Phidisa Conference in Richards Bay
May 2005	**Presenter** - IVRS – Clinphone**,** Study drug procedures / drug dosage adjustments – Investigator meeting for Hospital Acquired Pneumonia
August 2005	Endpoint Review Committee (ERC) & Data and Safety Monitoring Board (DSMB) – Poster presentation at the 2nd Annual Phidisa Conference in Cape Town
August 2005	Regulatory Milestones of Project PHIDISA – Poster presentation at the 2nd Annual Phidisa Conference in Cape Town
August 2005	A Descriptive Study of the Interpretations of the Regulations that Govern the Demographic Composition of Research Ethics Committees (RECs)/ Institutional Review Boards (IRBs) in South Africa. – Poster presentation at the 2nd Annual Phidisa Conference in Cape Town
August 2005	Serious Adverse Event Reporting . – Poster presentation at the 2nd Annual Phidisa Conference in Cape Town

February (02-03) 2006	**Presenter** Limiting missed visits, Principles of data collection presentation – Phidisa MOOP Training for Site Staff
February (10) 2006	**Presenter** - Role of CRO in Phidisa projects, 1 Mil Monitoring -Findings, Outcome and current perspective – Presentation at 1 Military Clinic staff retreat.
July 2006	The Utilization of Monitoring Benchmarks for Site Performance Evaluation in Project Phidisa – Poster presentation at the 3rd Annual Phidisa Conference in Port Elizabeth.
July 2006	Access to Supporting Documentation for Reportable Events: The Phidisa Experience - Poster presentation at the 3rd Annual Phidisa Conference in Port Elizabeth.
January 2007 (18) 2007	**Presenter** – Rota-037 South Africa update study progress at the 1st Africa Middle East Region CRA workshop for the rotavirus vaccine clinical trial
28-30 Sep 2007	Attended - 16th Annual Conference of the Society of Clinical Research Associates (SOCRA) in Denver, Colorado
11-12 October 2007	Monitors Meeting for benign prostatic hyperplasia trial in Greece
05 - 07 December 2007	Workshop – For HIV epidemiology and treatment study
03 – 05 March 2008	Workshop – Paving the way for HIV epidemiology and treatment study
Nov 2008	**Presenter** – GCP for Investigational site staff
09 July 2009	**Presenter** – Monitoring Project Phidisa – Induction Training for new site staff
May 2010	**Presenter** – Monitoring Project Phidisa – Induction Training for new site staff
27 – 29 September 2010	Workshop – Strategic workshop for Phidisa Project
03 -05 May 2011	Workshop – Strategic workshop for Phidisa Project
August 2011	**Presenter** – Monitoring Project Phidisa – Induction Training for new site staff
29 November – 02 Dec	Workshop – Strategic workshop for Phidisa Project

2011	
13- 14 September 2012	5th SACRA Clinical Trial Conference
09 – 12 October 2012	Workshop – Strategic workshop for Phidisa Project
13 September 2013	**Presenter** – Monitoring Project Phidisa – Induction Training for new site staff