CRISMO SITE PROFILE

2018

CLINICAL **R**ESEARCH **I**NVESTIGATOR **S**ITE **M**ANAGEMENT **O**RGANISATION

BERTHA GXOWA HOSPITAL RESEARCH CENTRE

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Executive Summary

Bertha Gxowa Research Centre is a research facility established by Clinical Research Investigator Site Management Organisation (CRISMO) which is a Site Management Organisation (SMO), established in South Africa. CRISMO is an SMO that is developing research centres in public hospitals/ clinic to provide a vehicle for capacity building, introducing clinical research to new investigators that had no means or structure and also increasing the participant/ patient pool in South African Clinical research.

CRISMO establishes the research centre in association with the interested departments within the hospital, forming an organization that provides collaborative work with clinical staff at hospital. This setting allows CRISMO to have access to different specialists that can be investigators for variety of therapeutic areas and access to diverse patient population.

CRISMO has secured its first site at Bertha Gxowa Hospital, the research centre located at the City of Ekurhuleni Health District building in the Bertha Gxowa Hospital premises: Villa Heidi building, on the ground floor, the structure is made up of an 118 square meters facility, which include 2 x consulting rooms; pharmacy room; storage room; monitoring room; toilet; kitchen and reception area and additional access to the boardroom. It has been set up to meet all the regulatory requirements for a research centre, equipment's including emergency trolley, 12 lead channel ECG machine, a centrifuge, continuous temperature monitoring device for the fridge and freezers, and a freezer than can go to minus 20 degrees and below.

The centre is fully capacitated with clinical research personnel, experienced Principal investigator, Dr MA Raphala, Dr Mamba and Dr Mathabathe. The past experience of the Dr's including participating in multinational clinical research studies at academic and private clinical research centres. More details highlighted in their CV's. In addition the site personnel also include Sub-Investigators, study nurse, pharmacists and study coordinators. Their roles and responsibilities will be highlighted in each CV.

The patient profile and patient access include that of diverse diseases areas. In addition the centre also has access to the 92 clinics located around Ekurhuleni area through its association with the family medicine department.

The centre provides sponsors with assurance of speedy recruitment to meet recruitment timelines, data quality, patient retention and above all ethics conduct of study, putting the patient first.

Company Aim and Objectives

CRISMO aims to accelerate scientific research through the provision of research infrastructure that will support the conduct of clinical research, and provide access to new patient population while creating a platform for new researchers and healthcare professionals to be involved in clinical trials.

CRISMO Objectives are:

1. To stimulate research related activities through capacity building initiatives.
2. To develop strategic collaboration with public and private health research organizations to develop and expand research opportunities.
3. To create professional and sustainable job opportunities in the clinical research profession.
4. To develop and expose health workers in research especially in the area of clinical trials.
5. To ensure broader participation of research volunteers in clinical research.
6. Lastly, to promote and support research activities within the Country.

CRISMO Principles are:

1. Respect and Trust _ Putting patient's first
2. Recognize patients as contributors to research and not as subjects
3. Provide care for clinical research participants
4. Produce quality data
5. Provide high recruitment
6. Adherence to all regulatory requirements and Good Clinical Practice

Site Location

Bertha Gxowa Research Centre, Bertha-Gxowa Hospital
Villa Heidi Building, Ground Floor,
Cnr Joubert and Hospital Street,
Germiston,
Gauteng, South Africa
1401

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Patient Profile and Patient Access

CRISMO Bertha Gxowa Research Centre is strategically located at Bertha Gxowa Hospital, which is a level 1 district hospital. The centre is also established in association with the Ekurhuleni Health District Family Medicine Department with plans to draw patients from the hospital and all the facilities that are associated with the Ekurhuleni Health District. The additional facilities are 8 Community Health Centre and 92 Primary Health Clinics. The primary health care facilities have an access of more than 1800 000 patients as per the year 2014-2015 report. The strategic relationship between the centre and the family medicine department will provide a relationship with health care workers that include clinical staff and nurses which will facilitate patient recruitment.

The centre aim to provide training to as many interested health care workers and get their involvement in clinical research and build capacity of investigators and research support staff.

The centre also aims to recruit patients from other hospitals associated with the district. A recruitment channel from all this hospitals has been established. This includes Tembisa Hospital, Thelle Mogoerane Hospital, Tambo Memorial Hospital, Far East Rand Hospital, Pholosong Hospital and Bertha Gxowa Hospital. A robust recruitment strategy has been put in place for ongoing clinical trials at this centre. These hospitals are equipped with specialists from Family Medicine, Internal Medicine, Obstetrics & Gynaecologists, Paediatrics, Cardiologist, Gastroenterologist, etc.

Title, Name & Surname	Role	Qualification	Clinical Research Experience	Last GCP	MPS	HPCSA/ Council registration
Dr Modikwe Aleck Raphala	PI / Director	MBChB, Bpham, FCP(SA)	Yes	03 Sep 2015	31 Dec 2017	Mar 2018
Dr. Musawenkosi Mamba	PI / SubI*	BSc, MBChB	Yes	19 Apr 2017	15 May 2018	Mar 2018
Dr Musawakhe Khanyeza	PI / SubI*	MBChB, MSc Pharmacology	Yes	09 Feb 2015	30 Sep 2017	Mar 2018
Dr Mohlamme Mathabathe	PI/SubI*	Bpharm, MBBCh, Diploma Tropical Medicind and Hygiene, MPH, and Msc Vaccicology	Yes	06 Sep 2017	31 Dec 2017	Mar 2018
Sr. Puleng Dhlamini	Nurse	BAcur, Advanced Diploma in Health Service Management Diploma in Nursing	No	23 Aug 2017	N/A	Yes
Sr. Nontuthuzelo Ngcobo	Nurse	Advanced Diploma Nursing, Psychiatric	No	23 Aug 2017	Denosa	Yes
Ms. Amukelani Rikhotso	Nurse*	Advanced Diploma Nursing, Neonatal	Yes	17 Sep 2015	Denosa	Yes
Mr. Mandla Nkosi	Pharmacist	Bsc, BPharm	Yes	17 Sep 2015	PSSA	Yes
Mr. Sandile Masimula	ACRC	N6 Human Resource Management	No	16 Jan 2018	N/a	N/a
Mr. Major Gama Cindi	CRC / SM	Postgraduate Certificate in Education, Data Management	Yes	17 Feb 2016	N/A	N/A

*additional sub-investigators will be introduced from the hospital database depending on the therapeutic area that each study will be working on.
*Additional Nursing staff_ will also be introduced depending on the studies awarded.
All the site staff are assigned per project. The above table indicate the main site staff only.

IATA training

The responsible site staffs that will be packaging the samples have completed the IATA training and certificate is filled in the Training folder at site.

Emergency Trolley and Emergency facilities

The site is equipped with an emergency trolley that contains all the required resuscitation material according to the MCC requirement published February 2016.
In addition, the site is less than 100 meters away from the Bertha Gxowa Hospital causality/ emergency area.

The site is running on a 24 hour Uninterrupted Power Backup System (UPS) installed for IP fridge and essential power supply equipments.

Standard Operating Procedures

CRISMO recognise the importance of having standards guidelines in handling and management of the research centres. The below is a list of SOP's that are already in place.

1. Site Staff Training
2. Informed Consent Process
3. Patient Recruitment Process and access to hospital database
4. Patient Safety including SAE Reporting Process
5. Investigational Product Handling
6. Emergency Procedure
7. Patient Retention
8. Source Notes and Data Management
9. Communication with IRB and the process of obtaining IRB Approval.
10. Delegation of Responsibilities
11. Training SOP
12. Quality control and Assurance
13. Archiving
14. Data Publication
15. SOP management process
16. Audits and Inspections
17. Site Monitoring
18. Confidentiality
19. Study Documents updates and Implementation

The SOP's are reviewed annually.
CRISMO will also make additional SOP with the guidance of sponsor's should there be additional requirements.

Capacity Building

CRISMO's main mission is increasing the foot print of clinical research in South Africa, reaching out to public institutions that do not have means, facilities and capabilities of setting up their own research unit and increasing patient participation in clinical Research.

Bertha Gxowa Hospital Research Centre:

1. Started operations in 2016
2. It is the first research site to be set up in a public hospital, Bertha Gxowa Hospital
3. The site is introducing new investigators who were sub-investigators at other centers as Principal investigators
4. The site staff who are sub-investigators, pharmacists and research nurses have no previous clinical research experience
5. The patients will also have access to potential treatment, majority of patients are new to clinical research.

Ethics submission process

The site is equipped to process its own Ethics submission. The sponsors/ CRO will be responsible for the cost of the application. The site will also charge a start-up cost that will include the ethics submission process.

The district research committee sits monthly to reviews all research projects that are conducted in their district facilities as such all research projects intending to recruit from public facilities should register with provincial health database.

Site staff Training

All site staffs are GCP trained. The GCP training will be renewed every 3 year cycle to comply with regulatory requirements.

The site staff will all receive protocol and study training before commencement of the study in line with the sponsor requirement. In addition the training SOP is in place at site and all site staff are trained on all SOP's.

Feasibility Process

The research Centre aim to provide the most accurate details to support feasibility process. The process will include review of medical data from the different unit following a request. Access to the district database has been granted to the site and it is facilitated through the family medicine department to give accurate information to support feasibility studies.

Informed consent Process

The detail is described as per the site SOP available upon request.

Study Conduct Management

A procedure is place to ensure conduct of the study. Obviously, all studies will be conducted in accordance with the protocol, local regulations and in compliance to all other applicable regulations and standards.

Patient Retention

Patient retention is as important as patient recruitment. Depending on the study, retention strategies will be put in place. It is important to retain patients in clinical trials to continue with contribution to data collection.

Quality control and assurance

Quality control measures and assurance has been put in place. This includes the SOP's that will be adhered to. The process of training and the details of the quality management are in the quality SOP.

Audits and Inspections

Audits and inspections are viewed as a free consultation; the site is always willing to receive this because it is taken as a learning process. The site will comply with the requirement for the visits.

The site prides itself of being audit ready at all times, doing the right thing at the very first time.

Conclusion

CRISMO is the only Site Management Organisation in South Africa that is committed to capacity building in the public health sector. Working with us will be partnering to contribute to the development of skilful workforce in the field of clinical research and creating a new pool of medical and scientific researchers.

We look forward to working with you on your future clinical research project.

Please send us your feasibility studies at info@crismo.co.za, our clinical manager will be happy to provide you with feedback promptly.

Thank you in advance for choosing CRISMO.