The University of KwaZulu-Natal (UKZN) is committed to meeting the objectives of Employment Equity to improve representivity within the Institution. Preference willbe given to applicants from designated groups in accordance with our EmploymentEquity plan

COLLEGE OF HEALTH SCIENCES

QUALITY ASSURANCE MANAGER X 1 (1-Year Fixed-Term appointment) DIABETES AND ENDOCRINOLOGY SCHOOL OF CLINICAL MEDICINE MEDICAL SCHOOL CAMPUS

REF NO.: T/CM12/2022

The Department of Diabetes and Endocrinology is seeking a dynamic and experienced individual to fill the position of Quality Assurance Manager for the DISCOVER ME-SOUTH AFRICA (DMSA) study, through a partnership between University of KwaZulu-Natal (UKZN). Inkosi Albert Luthuli Central Hospital (IALCH) / Department of Health (DOH) and Omnigen Biodata Limited, UK.

The aim of the study is to create a dynamic resource of demographic, health and geneticdata to understand clinical disease progression and informed risk prediction. The study will enroll up to 100,000 participants (patients) attending IALCH over a two-year period, and integrate their electronic health record (EHR) with genetic data. The incumbent will be based in Durban, at IALCH and Medical school Campus.

Job Purpose:

The role of the Research Quality Assurance (QA) Manager is responsible for the oversight, support and documentation of the day-to-day Discover Me-South Africa study research activities, to ensure the quality of the delivery of the study in accordance with the protocol and other relevant study documents

Duties and Responsibilities:

Primarily based in the laboratory but also working within a clinical setting alongside the study recruitment and enrolment team, the Research QA Manager will maintain standards for reliability and performance of the Discover Me-South Africa study in accordance with the study protocol and associated processes and procedures by:

- Performing quality assurance on laboratory sample processing and storage workflows
- Performing quality assurance on recruitment and enrolment procedures
- Supporting study staff with correctly performing day-to-day study activities
- Completing and maintaining study quality documents and files, including training records, maintenance documents and instrument books of life.
- Ensuring OHS and compliance with all facility health and safety laboratory protocols
- Escalating quality queries as per study procedures to the relevant personnel, as required
- Working closely with the South African study team and UK study team and sponsor to improve existing study workflows and procedures for efficient and high-quality delivery of different elements of the study
- Working closely with the South African study team and UK study team and sponsor to monitor risks relevant to study workflows and procedures
- Assisting with the monitoring of study inventory and maintenance of inventory documentation
- When required, assisting with the processing of study samples in the laboratory

Minimum Requirements:

- Masters (MSc) /qualified medical scientist / Medical Technologist (BTech)
- At least 2 years' experience in research or clinical trials in a quality assurance role; or
- At least 3 years' experience in research or clinical trials as a study monitor or clinical research associate (CRA); and
- A minimum of 3 years working in the clinical laboratory environment

Essential Requirements:

- Fluent in English and Zulu
- Excellent verbal and written communication skills
- Ability to deal with difficult or pressured situations
- Reliable and resilient
- Meticulous attention to detail
- Analytical and decision-making skills
- Good knowledge of Good Clinical Practice (GCP) and/or Good Laboratory Practice (GLP)
- Good knowledge of data protection, and relevant privacy legislation and requirements
- Proficiencies in MS Office Suite Word, Excel, MS Project, PowerPoint
- Ability to sit, stand and move around for long hours at a time

This post reports to the Local Principal Investigator. Enquiries regarding this post may be directed to Ms Nokahle Hadebe via e-mail: hadeben9@ukzn.ac.za.

The first three months of your employment will be a probationary period during which we will assess your suitability for the role. During the probation period, we reserve the right to end your employment with one week's notice.

The total remunerative salary is R345 242per annum. The closing date for receipt of applications is 5 June 2022. The University reserves the right not to make any appointment.

Applicants are required to complete the relevant application form which is available on the Vacancies website at www.ukzn.ac.za. Completed forms may be sent to hadeben9@ukzn.ac.za

The Advert Reference Number MUST be clearly stated in the email subject line.