

## CLINICAL RESEARCH ASSOCIATE

**Position:** Clinical Research Associate

**Overall purpose of the job:**

To assist the project management team in monitoring clinical trials within the region according to Good Clinical Practice (GCP) standards, with regards to the specific duties set out below, to a mutually agreed timetable and at places and dates agreed with the project management

**Key responsibilities:**

1. Provides GCP and project training to site staff.
2. Assists in development of associated study documents (Safety Monitoring Plans, Manual of Operations and Informed Consents).
3. Identifies site issues/problems, and associated root causes, and develops action plans to ensure resolution, including escalation of appropriate issues in a timely manner.
4. Acts as the main line of communication between the site and project manager.
5. Manages study sites to ensure site compliance with study protocols, GCP/ICH, and applicable regulations.
6. Conducts monitoring visits (Qualification, Site Initiation, Interim, Close-out, Audit Prep).
7. Generates clinical monitoring reports and follow up letters in a timely manner.
8. Verifies that all research staff and facilities have adequate qualifications and resources and are maintained throughout the course of the clinical study.
9. Verifies that the investigator and research staff follow the approved protocol and all GCP procedures.

**Minimum Requirements:**

1. Bachelor's degree in clinical, health, or life science or professional healthcare licensure with at least 5 years of clinical experience
2. Minimum of 5 years of related clinical research experience.
3. Fluency in written and spoken English
4. Thorough knowledge of ICH GCP Guidelines and FDA Regulations
5. Ability to prioritize.
6. Able to travel up to 75%, including internationally.

**Terms of Employment:**

Salary will be commensurate with skills and experience  
Contract is 1 year, renewable by mutual agreement and subject to exemplary performance, 3 months' probation, notice period 1 month.

**Applications should include the following:**

- Letter of Application
- Current Curriculum Vitae listing names of three references with contact details (Telephone and E-mail)
- Contact Telephone Number

Fluency in written and spoken French and Portuguese would be an added advantage/desirable. Knowledge of Ethics and Regulatory processes of African Countries would be an added advantage. Applicants from Anglophone, Francophone and Portuguese speaking Africa are encouraged to apply.

All applications should be through the Career page on our website at [www.aceresearchafrica.com](http://www.aceresearchafrica.com), to be received on or before 25<sup>th</sup> February 2017

