WINNIE OPONDO

Quality Assurance and Compliance Personnel

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ABOUT ME: Clinical Research Professional with experience in Clinical trial, quality assurance, data management, administrative tasks and regulatory compliance. Proven track record of ensuring adherence to ICH-GCP guidelines and delivery of high-quality data. Skilled in managing cross functional teams, resolving data discrepancies. Passionate about promoting patients' safety and driving successful trial outcomes

EDUCATION

Professional Certification in Data Science.
FEB 2025 – Ongoing
- ALX Africa

Post- Graduate Diploma in Clinical Research
March 2022 – June 2022
• International Clinical Research Academy
• Montrel, Canada.

Bachelor's Degree in Community Health and Development
Jun2013 – Sep 2017
• Great Lakes University of Kisumu
• Kisumu, Kenya.

SKILLS

- GCP knowledge
- Attention to details
- Time management
- Communication
- Adaptability
- Team Collaboration
- Data management
- Project management

RELEVANT TRAININGS

- ICH Good Clinical Practice E6(R3).
- Clinical Research Operations for Study Coordinator.
- Cyber Awareness Training.
- Introduction to Clinical Research.
- Trial Master File.

WORK EXPERIENCE

Walter Reed Army Institute of Research-Africa (WRAIR-A/ KEMRI)
Quality Assurance and Compliance Personnel

Date: March2024 - Present

- Monitor study team compliance with GCP and protocol - specific procedures, reducing audit finding by 25%
- Review patients' files for accuracy ensuring 100% compliance with regulatory guidelines.
- Conduct staff training sessions on quality assurance, improving documentation accuracy across teams.
- Assist in escalating and resolving compliance issues ensuring adverse events are reported to the IRB on time.
- Review participant files for accuracy and ensure specific visits on CRF are completed as per GCP standards and the current protocol.
- Assist in monitoring, documenting and reporting adverse events to IRB and Sponsor

Walter Reed Army Institute of Research-Africa (WRAIR-A/ KEMRI) ***Clinical Research Assistant***

Date: Jul2022- Feb2024

- Assisted with regulatory compliance review packages ensuring timely site activations
- Collaborate with internal departments to align site start up activities achieving 95% on time study initiation.
- Liaised with study coordinators and Principal Investigators to resolve data queries in real time, reducing discrepancies by 20%.
- Developed functional trackers to monitor study activities improving workflow.
- Works directly with participants recruiters to obtain documents related to study participants selection.
- Performs administrative duties on assigned trials as timely processing of documents for the study team such as CRFs and ICFs, distribution of work material to the study team.
- Provide system support ensuring that all subjects binder/files have been handed in to the data team for timely data entry.

- GCP for Clinical Trials with investigational drug and medical devices.
- GCP for clinical trials with Investigational Drugs and biologics.
- Human Research**.**

IT SKILLS

- **MS Office:** Word, Excel, Outlook, PowerPoint, Access
- **EDC:** Medidata Rave, Inform, Clinflash, REDCap
- **Google Drive:** Docs, Drive, Forms, Gmail, Sheets
- **Spreadsheets:** Excel, Google Drive, Open Office, pivot tables, vertical lookups, macros
- **Email**: Outlook, Gmail, mail merge, filters, folders
- **Presentations:** PowerPoint, Google slides, Tableau, Keynote
- **Operating systems:** Microsoft Windows,
- **Database management:** MS Access, MySQL, SQL.
- **eTMF: Montrium**

US Army Medical Research Unit- Kenya (USAMRD-K /KEMRI (The Walter Reed Project)

Research/Administrative Assistant

Date: Aug 2015 - Jun 2022

- Identification, randomization and selection of potential study participants from the active HDSS database for various studies in the research center.
- Perform QA/QC for both electronic related database and paper documents.
- Assist in query resolution from both electronic database and paper forms.
- Provide updated and approved study documents to the study team members for use in various study areas.
- Perform basic GIS to provide study team with study area maps, trace study participants to the household level using demographic information in the HDSS database hence reducing defaulters' rate.
- Ensure the availability and provision of study supplies and equipment in coordination with other relevant departments and nested studies for smooth running of the studies.

CUREENT TRIALS AM TAKING PART IN

1. **4202-HEM-301. (**May 2024 – Ongoing). An Adaptive, Randomized placebo -controlled, double blind, multi-center study of Oral FT-4202, a Pyruvate Kinase Activator in Patients with SCD sponsored by Forma Therapeutics **Role: QA/QC Phase: III Indication: Sick cell**
2. **CoVPN3008 (Ubuntu)** (JUN2022-Ongoing), Adults living with HIV COVID-9Mrna – 1273 sponsored by South Africa Medical Research Council. **Role: Clinical Trial Assistant Phase: III Indication: COVID-19**
3. **RV588 VAT 0008 COVPN-05** (Jul2021 – Ongoing) A parallel-group, multi-stage, modified double blind, multi-armed study to assess the efficacy, safety and immunogenicity of two SARS-CoV-2 Adjuvanted Recombination Protein Vaccine (monovalent and bivalent 0 for prevention against COVID-19 in adults 18 years and older sponsored by Sanofi.
   Role: Clinical Trial Assistant Phase: III
   Indication: COVID-19

REFEREES

Will be provided upon request.