SEGUN OGEDENGBE
240-883-8826 | onimaizz@gmail.com

SUMMARY:

- A competent professional with over 8 years of experience in Clinical Trials seeking a challenging position with the aim to broaden my experience in the field of clinical research and to promote safety, rights, and welfare of the study subjects by ensuring validity of data and making sure, that the study is conducted according to ICH-GCP guidelines.

SKILLS:

- Presentation, verbal and writing skills.
- Proficient in Microsoft Office, Word, Excel, Access, PowerPoint, and Outlook.
- Excellent organizational, multitasking, and analytical skills.
- Sound knowledge of Good Clinical Practices (ICH-GCP's) and FDA regulations.
- Use of Electronic Data Capture Systems (EDC): Medidata Rave, Inform, C3D
- Clinical Trial Management Systems (CTMS): eClinical and iMedidata
- Use of Patient Enrollment System: PRES
- Proficient in EMR system: Epic, OncoEMR, CRIS
- eRegulatory: Box, Florence, SharePoint, Shared Drive
- eTMF proficient: Veeva Vault
- Proficient in IVRS System
- IP Management tool: Vestigo Verify
- Detail oriented and a team player

THERAPEUTIC EXPERIENCE:

Oncology

- Cancer, Acute Lymphocytic Leukemia
- Cancer, Advanced Solid Malignancies
- Cancer, Non-Small Cell Lung
- Cancer, Breast
- Cancer, Colorectal
- Cancer, Metastatic Solid Tumors
- Cancer, Ovarian
- Cancer, Pancreatic
- Cancer, Prostate
- Cancer, Refractory Solid Tumors
- Cancer, Renal

Cardiovascular

- Congestive Heart Failure
- Essential Hypertension

CNS/Neurology

- Parkinson’s Disease
- Depression
- Pain
- Headache

Endocrinology

- Diabetes
- Growth Hormone Deficiency

Infectious Disease

- Infection, Influenza
- Infection, Common Cold

Medical Device

- Continuous Glucose Monitoring Device

Ophthalmology

- Dry Eye
- Glaucoma

EXPERIENCE:

08/2022 till date **NATIONAL CANCER INSTITUTE | NATIONAL INSTITUTE OF HEALTH**
Senior Clinical Research Associate

- Monitor NIH intramural and extramural multi-institutional research protocols and ensure clinical trials are conducted in a timely manner.
- Provide quality control of the data and compliance with regulatory requirements on various NIH research protocols.
- Assure compliance with institutional Standard Operating Procedures (SOPs) and Policies, protocol requirements, and institutional reporting requirements.
- Development of data handling guidelines to check validity of clinical data.
- Assure project and study timelines are met.
- Recognizing clinical values and identify data or patient safety issues.
- Prepare and perform SIV, routine SMVs and SCV for each of assigned studies.
- Review clinical study related documents including the Informed Consent Forms (ICF), source documents, patient instruction guides and Case Report Forms (CRFs).
- Assist in investigational site identification and perform site qualification visits if needed.
- Monitor progress of clinical studies, develop progress reports for the investigator (e.g., patient accrual, audit reports and findings, data transmission and data reporting activities).
- Ensure quality of data generated from clinical sites and assist in resolving patient eligibility and protocol deviation issues.
- Serve as liaison and resource for assigned investigational sites.
- Analyze monitoring findings, identify, and report trends, and make improvement recommendations to management.

11/2018 to 07/2022 **NOVUM PHARMACEUTICAL RESEARCH SERVICES**
Senior Clinical Research Associate

- Scheduled and conducted PSSV, SIV, IMV, and COV in a timely manner.
- Performed and coordinates trial process according to Protocol, ICH-GCP guidelines and SOP.
- Verifies CRF/eCRF with source data for consistency.
- Participates in Sponsor and Investigator/Initiation Meetings.
- Ensures reports and trainings are completed and submitted in a timely manner.
- Ensures study supplies (lab kits) are available on site and IP accountability/inventory, security, dispensation, return and destruction (where applicable) are in compliance with the protocol and site SOP.
- Ensures Adverse Events and Serious Adverse Events are reported according to protocol/ ICH-GCP guidelines.
- Reviews protocol violations and implement corrective measures such as training the site personnel to prevent future occurrence.
- Follow-up site issues and action items per company/sponsor timeline(s).
- Escalate concerns/potential risks, document observations, recommendation and ensure prompt resolution of concerns/issues.

- Ensures study documents are in place prior to site initiation/study enrollment and throughout the study
- Assists, trains, mentor and lead other Monitors.

07/2014 to 11/2018 **PRA HEALTH SCIENCES INC.**
Clinical Research Associate I/II

- Performed site selection, initiation, monitoring, and close-out visits, and maintained appropriate documentation.
- Established regular lines of communication, administered protocol and related study training to assigned sites.
- Evaluated the quality and integrity of site practices and appropriately escalated quality issues.
- Managed progress by tracking regulatory submissions, recruitment, case report form (CRF) completion, and data query resolution.
- Assisted the Clinical Trial Manager with all aspects of the design, start-up, implementation, management, and closeout of clinical studies.
- Coordinated efforts from study start-up through close-out, including collection and review of regulatory documents.
- Monitored assigned clinical trials and evaluated clinical data, to ensure compliance with study protocols, FDA regulations, and overall clinical objectives.
- Monitored clinical trials to ensure that sites are meeting its enrollment goals and the study is being conducted in a manner consistent with the protocol, ICH-GCP, and all applicable ethical guidelines.
- Assisted with identification and recruitment activities for investigative sites.
- Performed pre-study visits to evaluate the suitability of potential investigational sites; conducted initiation visits and ensured the site has received all the necessary tools and supplies for the successful execution of the clinical study.
- Tracked all protocol deviations and Serious Adverse Events and ensured they were properly documented and promptly reported to the IRB and the sponsor.
- Ensured timely submission of all monitoring reports including all expenses.
- Functioned as the first line of contact for the site personnel to resolve all protocol specific and other trial related issues or questions.

01/2010 to 11/2013 **PFIZER GLOBAL PHARMACEUTICALS/W. AFRICA**
Territory Manager

- Generated demand for Pfizer products through target detailing of niche customers.
- Identify key opinion leaders (KOLs) and developed valuable long-term relationships by providing expertise and education on new advances in cardiovascular disease management.
- Facilitated opinion leader development and aid in the identification of areas of mutual interest and collaboration.
- Provided timely, accurate, specific, and balanced responses to KOLs' request for information.
- Conducted educational marketing for stakeholders including physician and other healthcare professional and patient forums.
- Implemented strategies to achieve quarterly sales target.
- Analyzed sales and marketing data for actionable intelligence report on competition's activities.

EDUCATION:

Doctor of Pharmacy
Massachusetts College of Pharmacy and Health Sciences

Bachelor of Science, Pharmacy
Obafemi Awolowo University