OLUWOLE. OSHUNSANYA MD, PH&TM

Phone: (504)-237-5935. Oluwole.Oshunsanya.MD@outlook.com

Medical doctor, with extensive experience in providing outstanding clinical, research and pharmacovigilance expertise who seeks to add value to organizations while growing with the organization.

PROFESSIONAL SKILLS

- Proficient in adverse event review and causality assessment, expectedness, and MedDRA coding.
- Proficient in Oracle Argus, Lifesphere Multivigilance/ArisG, Medidata Rave, Epic and Cerner EMR.
- Self-motivated with great organizational and problem-solving skills.
- Able to learn and convey medical information effectively.
- Able to multi-task while maintaining strict attention to detail.
- Mature, sound decision-making skills.
- Therapeutic Areas: Tropical medicine, Infectious Diseases, Vaccine development, Neurology and Oncology.

PROFESSIONAL WORK HISTORY

IQVIA Life Sciences Solutions - Remote based **June 2022 –till present.**

Safety Lead/ Safety Program Manager

- Providing leadership for Pharmacovigilance virtual project teams by keeping local/global Lifecycle Safety team current on project developments.
- Leading internal Pharmacovigilance team meetings to review project processes and status by working closely with Pharmacovigilance Safety Operational teams, to ensure projects/programs are delivered in accordance with customer expectations.
- Facilitating sales activities, and sales presentations (capabilities, bid defenses) and proposal development (strategy, costs and text).
- Developing customer relationships into partnerships; manage accounts targeting extended business relationship throughout lifecycle.
- Facilitating discussions on new business opportunities with existing customers.
- Managing finances for assigned projects/programs which includes updating financial systems, revenue recognition, invoicing, project budget review, project financial analysis, pursuit of change orders.
- Managing customer deliverables for assigned projects/programs which includes tactical, day-to-day customer-facing leadership at project/program level.
- Performing project planning (timelines, deliverables), scope management, quality management and project financial management.
- Accountable for the management and service delivery of a range of large sized regional and global projects as assigned, covering single or multiple Lifecycle Safety functions (clinical trial and / or post-market).
- Providing leadership and accountability for customer-facing activities and oversight of operational service delivery, working cross-functionally and across the opportunity lifecycle, integrating delivery into one seamless and transparent program for customers, aligned by accounts.
- Collaborating with global management team and integrated partners to develop and implement strategic initiatives/solutions to expand business, partnership, strengthen overall relationship and ensure global consistency.

IQVIA Life Sciences Solutions - Remote based **Jan 2021 – Jan 2022**
Medical Safety Advisor/ Drug Safety Physician

- Performed individual case safety assessments of causality, expectedness and seriousness.
- Responsible for medical review of serious adverse events and non-serious adverse events from spontaneous reports in support of drug safety activities for clients.
- Processed safety reports for complete accuracy against source documents including preparation of queries to obtain missing information necessary for reviewing the adverse event.
- Ensured the medical accuracy of the narrative and create medical assessments and comment on individual safety reports.
- Performed qualitative and quantitative signal detection.
- Attended and participated in signal detection meetings with team leads.
- Processed SUSAR cases from various sources such as clinical trial, post-marketed, literature solicited, non-serious and serious adverse event cases.
- Provided medical, clinical and scientific advisory expertise in clinical research studies and post marketing programs.
- Reviewed and approved Analysis of Similar Events and provide company comments and assessment with medical analysis for SUSAR/IND Safety Reports
- Conducted aggregate safety analysis utilizing case-level review of internal clinical and safety databases, literature searches, and industry emerging trends and best practices.
- Participated in writing safety aggregate reports (DSUR, PSUR & PBRER).
- Performed medical review for case narratives and promotional materials.
- Performed quality control and review of ICSR and random case reviews.
- Performed medical and safety monitoring on assigned projects.
- Supervised quality control for newly hired medical safety advisors.
- Provided therapeutic area/indication training for new hires and continuous improvement.
- Reviewed laboratory values, adverse events, coding dictionaries and data tables, listings and figures as needed to identify drug safety issues in collaboration with the project physician.

Clinical Trial Unit (CTU)-Tulane University –New Orleans, Louisiana **Oct 2020 – Jan 2021**
Senior Clinical Research Coordinator/ Safety Monitor.

- Determined the eligibility and supported the recruitment of research participants.
- Coordinated the regulatory processes as they relate to the evaluation, initiation, maintenance, closure and internal/external audit of clinical trials and other research activity.
- Coordinated and managed study participant activities as it relates to the conduct of research and clinical trials.
- Oversee the preparation and maintenance of required study and regulatory documentation, e.g., reports for Competent Authority submissions, Monitoring Plan, Pharmacy Manual, Investigator contracts and budgets.
- Reviewed and identified project study trends and proactively responds to client and team members.
- Manually input of patient medical information in to the safety data base.

- Developed and maintained all required documentation as it relates to the conduct of assigned clinical trials and associated patient care.
- Screened, enrolled, and followed study patients, ensuring protocol compliance and close patient monitoring.
- Reviewed and interpreted the patient's lab information to ensure compliance with the study protocol.
- Reviewed advises events with PI and followed the recommendation in the protocol on how to handle SAE
- Reported serious adverse events to the principal investigator, IRB and site monitor per protocol.
- Worked closely with other medical monitors to ensure that documents (protocols, Informed Consent document (ICD) etc.) meet regulatory requirements and company policy and has been reviewed by IRB/IECs.
- Conducted daily work and clinical trial activity in accordance with Good Clinical Practice Guidelines.
- Provided mentorship, professional development and support to Clinical Research Coordinators.

Kaonic Clinical Research- Remote based **Jan 2018 – Dec 2020**
Medical Safety Reviewer

- Performed individual case safety assessments of causality, expectedness and seriousness.
- Responsible for medical review of serious adverse events and non-serious adverse events from spontaneous reports in support of drug safety activities for clients.
- Processed safety reports for complete accuracy against source documents including preparation of queries to obtain missing information necessary for reviewing the adverse event.
- Ensured the medical accuracy of the narrative and create medical assessments and comment on individual safety reports.
- Processed safety reports for complete accuracy against source documents including preparation of queries to obtain missing information necessary for reviewing the adverse event.
- Performed medical review for case narratives and promotional materials.
- Performed quality control and review of ICSR and random case reviews.
- Performed medical and safety monitoring on assigned projects.
- Reviewed laboratory values, adverse events, coding dictionaries and data tables, listings and figures as needed to identify drug safety issues in collaboration with the project physician.
- Performed quality check of ICSRs.
- Wrote accurate and detailed clinical case narratives, assessing causality, and writing CIOMS comments as required.
- Accurately captured Listedness/expectedness of adverse events, researching USPI and company core datasheet.

Herzing University-Kenner, Louisiana **Jan 2014 – April 2020**
Program Chair/Associate Professor

- Prepared and presented lectures to Nursing students, patients, and health care practitioners.
- Researched and compiled bibliographies of specialized materials for reading assignments to stimulate class discussions and research statistics.
- Managed staff development and training.
- Provided academic advising for students.

- Oversaw instructional design for students in Pathophysiology, Pharmacology, Microbiology and Anatomy and Physiology.
- Worked with other faculty members to evaluate, revise, and develop curricula and pedagogical methods that enhance student mastery of course content and student success after they enter a health science program, such as nursing or allied health.
- Supported the mission of the department and college to promote student learning through quality instruction, curriculum enhancement, faculty scholarship, professional development and service to the college.
- Served on collegewide and departmental committees, councils, workgroups, and task forces.

GlaxoSmithKline- Lagos **Nov. 2010 – Dec. 2013**
Drug Safety Associate

- Maintained a thorough knowledge of NAFDAC, ICH guidelines initiatives and regulations governing both safety reporting and processing for the clinical trial environment as well as the post-market environment.
- Assigned priority to incoming events and classified them according to regulatory reporting.
- Reviewed and compiled adverse event data and produced a report.
- Evaluated cases for seriousness, relatedness, and expectedness according to the protocol, investigators brochure, and/or packet insert.
- Reviewed clinical study adverse events for accuracy, integrity, consistency according to project-specific guidelines.
- Generated queries using ARGUS to obtain missing case information.
- Entered data for incoming cases into Argus safety database, coding events (MedDRA) and WHO-DD.
- Performed electronic and manual coding as necessary.
- Reviewed relevant source documents for consistency and verification of adverse event data.
- Prepared narratives according to an approved template.
- Adhered to required timelines for the completion of an adverse event report.

General Hospital, Lagos **Nov 2006 – Dec 2013**
Medical Officer

- Conducted daily ward rounds and clinical rotations in various Medical and Surgical departments.
- Consulted with patients at the accident /emergency and various clinics under different departments such as Medicine, Surgery, Obstetrics and Gynecology, Pediatrics.
- Managed the recruitment of patients for clinical studies under Hematologic/ oncology/ infectious disease departments to increased patient participation.
- Managed a disease outbreak in a rural setting, investigated outbreaks, and conducted health education seminars.
- Conducted research regarding the need for new diagnostic equipment for the hospital.
- Developed treatment plans for patients with chronic conditions, including high blood pressure, diabetes, heart disease, and other problems with internal systems.
- Reviewed medical records and charts of each patient before and during a visit to understand health history, record actions, and maintain accurate information.
- Diagnosed specific medical conditions based on observation, physical examination, wellness history, and patient concerns.

- Conducted studies and performed other analytical work related to the planning, development, organization, administration, evaluation, and delivery of public health programs.
- Presented at clinical seminars, grand rounds, and morbidity and mortality reviews.

EDUCATION

Master of Public Health & Tropical Medicine ~Tulane School of Public Health and Tropical Medicine University. U.S.A.
Medical Doctor ~University of Ilorin, Nigeria.

TRAINING AND CERTIFICATIONS

Signal Detection and Data Mining- DIA training.
Medidata Rave® Certified Clinical Research Coordinator.
Good Clinical Practice Certification- NIDA Clinical trial network.
Signal detection and Causality assessment -Uppsala Monitoring Centre.
Graduate Certificate, Advanced Drug Safety & Pharmacovigilance.
Educational Commission for Foreign Medical Graduates (ECFMG) Certification.