Vanessagold Oben

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Enthusiastic Senior Clinical Research Associate eager to contribute to team success through hard work, attention to detail and excellent organizational skills. Well-versed in study protocols, standard operating procedures and general trial oversight. Excellent problem-solving abilities with a detail-oriented nature. Ready to bring 6 years of related experience to a challenging new role.

Work Experience

Clinical Research Associate

Merck - Houston, TX
January 2019 to Present

· Provides input to the site selection process on appropriate/inappropriate sites.
· Conducts remote site qualification visits as required per study monitoring plan.
· Informs Study Manager and works to resolve issues related to challenging/frustrated/irate investigators/ staff.
· Troubleshoots enrollment difficulties.
· Assists in preparing sites for audits and in resolving audit action items.
· Performs and summarizes literature searches.
· Assists Study Manager with development of human clinical protocol, investigational plan/brochure and study operations development.
· Supports Study Manager in developing SIV agenda, presentation (protocol, GCP, etc.), and other training materials.
· Responsible for training Merck Clinical Research Staff.
· Responsible for creation of tracking tools and reporting of department metrics.

Clinical Research Associate I

Parexel - Houston, TX
January 2018 to March 2019

· Read and understood all study-related material and function-related SOPs.
· Prepared confirmation and follow-up letters in accordance with the applicable
Parexel SOPs and study-specific plans.
· Prepared visit reports according to applicable SOPs and study-specific plans.
· Interacted with the study team to communicate visit findings, and CRO representatives, when necessary, to ensure program success through ongoing communication.
· Completed training assigned by Parexel, as necessary, including general training requirements, SOPs, and system and process related training.
· Adheres to Parexel SOPs and processes.
· Collaborated with clinical study site and sponsor to troubleshoot and provide solutions to study-related issues.
· Coordinated and scheduled protocol-related visits and required testing to demonstrate vigilance in patient safety, protocol compliance and data quality.

· Implemented electronic data capturing systems to adhere with clinical research guidelines.

Clinical Trial Associate

Parexel - Houston, TX
January 2016 to January 2018

· Reviewed and/or approval of study documentation, including essential document packets, study plans, informed consent forms, etc.
· Supported oversight of risk-based monitoring.
· Attended key team meetings as required.
· Supported regulatory inspection readiness (e.g. preparation of materials and/or participation during regulatory inspections.)
· Supported additional ad-hoc activities as needed, as agreed with CTA Manager.
· Collaborated with internal departments (Legal, Insurance, R&D functions, etc.),
CROs, and external vendors.
· Supported vendor contract administration as required.
· Provided support for departmental tasks.

Clinical Research Coordinator

MD Anderson - Houston, TX
January 2014 to January 2016

· Handled administrative activities generally associated with the conduct of clinical trials.
· Provided guidance to less experienced staff.
· Managed research project databases, develops flow sheets and other study related documents, and completes source documents/case report forms.
· Interfaced with research participants, determines eligibility and consents study participants according to protocol.
· Approved orders for supplies and equipment maintenance.
· Assisted in developing recruitment strategies and conducting screenings for study participants including interviews and questionnaires.
· Supervised collection of study specimens and processing.
· Established case packages for study procedures, monitored scheduling of procedures and charges, coordinated other services as needed.
· Ensured compliance with research protocols, reviewed case report forms and audits for accuracy with source documents, attended monitoring meetings with sponsors.
· Prepared regulatory submissions.

Education

Bachelor of Science in Environmental Sciences

University of Buea

Skills

- 6 years of site management and clinical research experience.
- Excellent knowledge of FDA regulatory requirements, GCP/ICH guidelines, and general medical terminology.
- Excellent organization and problem solving skills.

- Ability to work independently, as well as handle a number of diverse projects simultaneously, under tight time constraints.
- Ability to engage and demonstrate cooperative behavior to support team efforts.
- Experience in responding rapidly to changing priorities and in managing aggressive deadlines.
- Excellent written and verbal communication skills.
- Demonstrated experience in leading and participating in collaborative work teams.
- Strong leadership abilities and interpersonal skills.
- Experience in managing multiple tasks.
- Phase I-III clinical trial experience.
- Ability to perform up to 80% of nationwide travel.
- Neurology: Bipolar Disorder, Major Depressive Disorder, Parkinson Disease, Multiple Sclerosis and Migraine
- Medical Device: In Vitro Diagnostics
- Oncology: Glioblastoma, Solid Tumor, Acute Myeloid Leukemia, CAR-T Cell Lymphoma, Prostrate Cancer and Colon Cancer
- Infectious Disease: Flu and COVID-19
- Metabolic and Endocrinology: Diabetes