EMILY **MINKAH - PREMO, BPharm, MPH**

Clinical Research Associate

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SUMMARY OF QUALIFICATIONS

- Clinical Research Associate (CRA) with 7+ years of experience in designing, managing, and analyzing clinical trials; with a demonstrated proficiency in regulatory compliance, data management and stakeholder coordination; and a proven track record of improving study efficiency, accuracy and outcomes, encompassing the USA, Germany and China.
- Spearheaded and managed comprehensive clinical research initiatives, including projects with UNICEF aimed at reducing HIV transmission, achieving a significant reduction in new HIV cases through innovative interventions.
- Directed and orchestrated complex cancer trials, particularly in pancreatic cancer, utilizing advanced data analysis methodologies to drive evidence-based outcomes, ensuring rigorous adherence to GCP, ICH guidelines, and FDA regulations.
- Established a robust track record in regulatory compliance, meticulously overseeing the preparation and submission of study documentation to regulatory authorities, demonstrating proficiency in navigating complex regulatory landscapes to ensure ethical conduct and adherence to global standards.
- Directed post-market surveillance for Bayer Anti-Allergy and Cardiovascular medication portfolio, developed Risk Management Plans (RMPs) that reduced product-related safety incidents by 20% and created SOPs for medication quality checks, ensuring a 100% compliance with local and global regulations.

SKILLS

Software : Microsoft Office - Google Suite - CRM - Konka - Talus - R - SAS - STATA - SQL - RedCap - EHR
Industry: Clinical Trial Management - Regulatory Compliance (GCP, ICH Guidelines) - Protocol Design and Development - Data Management - Statistical Analysis - Quality Control and Assurance - Electronic Trial Master File (eTMF) Management - Project Management - Health Policy Analysis - Epidemiological Study Design - Data Visualization - Public Health Surveillance System - Clinical Data Monitoring - Scientific Writing

PROFESSIONAL EXPERIENCES

CLINICAL RESEARCH COORDINATOR | George Washington University | Washington DC *Sep 2021 - May 2024*

- Directed the collection, analysis, and management of data for UNICEF projects aimed at reducing HIV incidence, implementing advanced data management protocols to achieve a 98% data accuracy rate, and engineered protocols that reduced HIV transmission rates by 20% over two years.
- Coordinated site selection, initiation, and activation for over 10 clinical trials, including an intervention to increase antiretroviral medication adherence among injectable drug users in rural Appalachia, achieving 100% site activation within timelines and reducing start-up delays by 20%.
- Analyzed large-scale clinical trial data using advanced epidemiological methods and SAS, including managing data for multiple trials and conducting a meta-analysis on RSV prophylaxis, which improved data accuracy by 15% and supported successful regulatory submissions.
- Led the development and execution of a multi-center, assessor-blinded phase trial protocol comparing the efficacy and safety of an intervention for reducing violent behavior in adults with psychosis and cannabis use, ensuring 95% compliance across all sites.
- Prepared and reviewed regulatory documents, such as site regulatory documents and IRB/EC submissions, maintaining a 98% approval rate on first submissions.
- Led the design of a protocol and clinical trial methodology tailored for pancreatic cancer, and authored a press release outlining the impact of red and processed meat on cancer prevention and treatment strategies.
- Conducted comprehensive research using the SEER database to study ovarian cancer trends, identifying high-risk populations.

CLINICAL TRIAL ASSOCIATE | Children's National Hospital | Washington DC *Jan 2023 - May 2024*

- Directed and coordinated clinical research activities at a leading hospital in Washington, focusing on the pediatric unit's research department, including oversight of study initiation, monitoring, and close-out activities.

- Led cross-functional teams in planning, executing, and analyzing longitudinal studies within the FLiPRx project, managing data from over 200 patients using statistical methods such as regression analysis and survival analysis.
- Ensured rigorous compliance with ICH-GCP guidelines and local regulatory requirements, overseeing the preparation and submission of IRB/EC documentation and maintaining accurate study records.
- Implemented data management strategies to optimize data quality and integrity, collaborating with clinical teams and data managers to resolve queries and discrepancies promptly.
- Developed and successfully secured funding through a competitive grant proposal, enabling the expansion and continuation of research efforts, showcasing strong project management skills.

PHARMACOVIGILANCE & REGULATORY AFFAIRS SPECIALIST | BAYER | Germany *Nov 2016 - Jan 2020*

- Directed post-market surveillance and signal detection for Bayer Anti - Allergy and Cardiovascular medications, conducted data collection and developed Risk Management Plans (RMPs) that reduced product-related safety incidents by 20% and enhanced overall pharmacovigilance quality.
- Created and implemented Standard Operating Procedures (SOPs) for medication quality checks, and orchestrated the prompt submission of drug registration applications, achieving a 95% adherence rate to regulatory timelines, minimizing operational disruptions for Bayer.
- Ensured 100% compliance with local and global regulations and overseeing submission processes resulting in zero revenue loss from license expiration due to proactive renewal submissions.
- Led educational sessions for healthcare professionals, boosting knowledge and adherence to safety protocols, and successfully onboarded over 10 major hospitals, expanding market reach and product adoption.
- Improved supply chain and inventory management, increasing operational efficiency by 25% and ensuring no product holds during tenure.

PHARMACOVIGILANCE ANALYST | Sanisphere | Hong Kong, China *Jun 2015 - Nov 2016*

- Led the post-market surveillance of pharmaceutical products, systematically collecting, analyzing, and reporting adverse events for both prescription and non-prescription medications to regulatory authorities, ensuring compliance with global pharmacovigilance regulations.
- Conducted thorough data collection on medication types, market availability, and authenticity, ensuring the integrity of safety data for both brand-name and generic drugs.
- Conducted comprehensive risk assessments and signal detection activities, identifying potential safety concerns and implementing risk mitigation strategies.
- Improved supply chain, inventory, and management systems, leading to a 20% reduction in product-related safety incidents and a 25% increase in operational efficiency.
- Collaborated with cross-functional teams, including clinical, regulatory, and medical affairs, and mentored new analysts and conducted pharmacovigilance training programs, enhancing team capabilities.

EDUCATION

Masters of Public Health in Epidemiology (MPH) / George Washington University, USA *Aug 2022 - Aug 2024*

- Relevant Courses : Biostatistics, Advanced Epidemiology Methods, Drug and Vaccine Safety Epidemiology, Clinical Trials, Regression Analysis, Survival Analysis, and Applied Epidemiology Data Analysis.

Bachelors of Pharmacy (BPharm) / University of Ghana, Ghana *Sep 2011 - May 2015*

- Relevant Courses : Pharmacology, Pharmaceutical Science, Pharmacoepidemiology and Biostatistics.
- Led a research project on quality control of psychotropic medications on the market, focusing on regulatory standards and overall pharmacovigilance quality.

Advanced Pharmacovigilance and Argus Safety Certification (CRPS) *Apr 2024*
Advanced ICH GCP Certifications *Apr 2024*
Licensed Pharmacist *Jan 2017*