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Career Summary

Accomplished and results-oriented Ph.D. Scientist/Clinician with comprehensive experience in leading and monitoring clinical research, and formulating standards and guidelines for clinical research services and programs.

Highly qualified science liaison with proven success in establishing and maintaining key relationships among national scientific thought leaders to ensure a thorough understanding of all relevant scientific product knowledge. Solid history in facilitating patient access and adherence to therapy and instructing HCP offices and community to enhance awareness of disease states and undiagnosed disease. Expert in oncology/hematology, cardiac/neuroscience research, phase I-IV clinical trials, and academic nursing education as well as engaging and establishing relationships with stakeholders, key opinion leaders, and key decision-makers at various organizations. Experience in communicating with oncology/hematology, cardiovascular, and neuroscience interdisciplinary team through strong networking and cross-functional partnerships. Deft at collaborating with field sales, market access, patient services, and other client colleagues to accomplish goals and objectives.

- In-depth knowledge of developing plans, executing methodologies, writing reports, and presenting research findings to management.
- Instrumental in coordinating a clinical research study by identifying patients, tracking inventory, interacting with patients, collecting data, and overseeing protocols.
- Adept at providing clinical leadership and medical strategic input for all clinical deliverables in the assigned project and steering development of clinical sections of trial and program level regulatory documents.
- Demonstrated ability to direct and execute clinical research plans and programs according to established design principles.

Areas of Strength

- Exceptional Patient Services
- Oncology & Hematology
- New Policies & Procedures
- Clinical Scientific Acumen
- Cross- Functional Management
- Matrix Management
- Patient Coaching & Mentoring
- Counseling & Staff Development
- Community Relationship Management
- Regulatory Compliance
- Data Management & Submission
- Research & Mitigation

Education & Credentials

University of Maryland School of Nursing, Baltimore, Maryland **| Ph.D. – Nursing (2018)**

University of Maryland School of Nursing, Baltimore, Maryland **| Community Public Health Nursing (2010)**

Simmons College, Boston, Massachusetts **| Bachelor of Science in Nursing (2005)**

Indiana University, South Bend, Indiana **| Bachelor of General Studies (1999)**

Trainings: GCPs/ICH Guidelines | CAPA | FDA Guidelines (21CFR Part 50, 54, 56, 312) | HIPAA Regulations | NIH Certification – Protection of Human Research Participants | SOPs | Fraud & Misconduct | Regulatory Documents – Review & Processing | SAE-Review, Reporting, & Handling | GCP/ICP/FDA/IRB Regulatory Principles | JCAHO, IRB, Risk Management, & Quality Improvement | Study Design Methodology & Data Analysis-Qualitative & Quantitative | Medicaid & Medicare Billing Procedures, Policies, & Regulations | Quicken Books & Accounting Processes

Professional Experience

2018 to Present: Novartis Pharmaceutical Corp., Mid-Atlantic Region
➲ **Patient Services Coordinator II-Neuroscience**

Provide exceptional customer service and education to the customer as well as direct and monitor physician offices in a defined geographical region. Streamline smooth running of business operations by facilitating patient access and adherence to therapy and instructing HCP offices and community to enhance awareness of disease states and undiagnosed disease. Optimize business performance by identifying and resolving issues impacting treatment initiation and ongoing therapy. Develop and maintain strong and corporate relationships with community-based HCPs, including MDs, NPs, Pas, and nurses. Create and deliver a learning series on Phase I-IV clinical trials by serving as a subject matter expert.

Key Duties:

- Attained organizational objectives by collaborating with field sales, market access, patient services, and client colleagues.
- Assured that the efficient onboarding process by coordinating with field reimbursement managers.
- Selected digital champion for Southeast region-catalyst for technology-enabled change.
- Deliver approved product and disease state-related education to healthcare professionals (HCPs) within assigned geographic region.

Key Accomplishment:

- *Through collaboration with Sales Representative increased TRX by **90%** for Aimovig in Q3-4 2019.*

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- *Increased engagement with KOLs by **80%** through collaboration and partnership with sales leading to president club award for sales rep. I accompanied sales rep on president's club in 2019.*

2017 to 2018: Ashfield Healthcare, Mid-Atlantic Region
➲ **MS Clinical Nurse Educator for TEVA**

Provided education for the launch of Austedo - Neuroscience. Educated HCP offices and community to increase awareness of disease states and undiagnosed disease. Communicated and collaborated with Field Sales, Market Access, Patient Services, and other colleagues to achieve goals and objectives. Identified and resolved issues impacting treatment initiation and ongoing therapy.

Key Duties:

- Boosted awareness of disease states and undiagnosed disease by instructing HCP offices and community as well as delivered education for the launch of Austedo - Neuroscience.
- Partnered with commercial team members, sales, marketing, managed markets, patient advocacy, as well as medical counterparts, and medical affairs.
- Responsible for establishing strategic relationships with key customers, local and regional advocacy organizations and the oncology nursing community.
- Developed strong long-term relationships with clinical personnel, advanced practice provider opinion leaders, key nurse opinion leaders, advocacy organizations, key nursing organizations, and societies focused on the nursing segment.

2017: Ashfield Healthcare, Mid-Atlantic Region
➲ **MS Clinical Nurse Educator for Genentech**

Served as point of contact/clinical expert and targeted physician offices to assist with patient access and adherence to therapy. Provided education for the launch of Ocrevus - Neuroscience. Communicated and collaborated with field sales, market access, patient services, and other colleagues to achieve goals and objectives. Identified and resolved issues impacting treatment initiation and ongoing therapy. Performed various tasks, including making regular office calls, concentrating on the whole office, and organizing education on client products, comprising potential adverse events and safety issues.

Key Duties:

- Enhanced the awareness of disease states and undiagnosed diseases by educating HCP offices and the community.
- Identified and developed all available resources and fulfilled with codes of conduct and applicable regulations/legislation.
- Created a collaborative approach that served to provide education, enhanced clinical care, and the opportunity to build loyal customers and business relationships, and worked cross-functionally as part of an integrated team to identify and access key customers, assess their education needs, and provide clinical and educational support.
- Educated and trained clinical personnel in the delivery of therapies, patient treatment management, and related clinical topics in support of the mission.
- Represented specified therapeutics products in the medical community for an assigned geographical area in accordance with companies direction and policy, focused on the nursing segment.

2017: DP Clinical Inc., Mid-Atlantic Region
➲ **Safety Monitor**

Improved organizational performance by creating and implementing departmental standard operating procedures (SOPs). Designed detailed reports and directly delivered at the bid-defense meetings with potential clients. Analyzed medical coding for accuracy and completeness by coordinating with clinical data management as well as collaborated with principal investigators and sub-investigators on all facets of clinical research studies. Delivered exceptional services within the company by formulating and implementing patient screening and recruitment documents for clinical trials. Supported in development annual reports and DMC reports as well as conduced and spearheaded training programs for the team of staff members on safety monitoring. Managed several responsibilities, such as completing paper and electronic case report forms, owning a confidential database with patient information, and executing protocol data collection and query resolution. Devised and completed MedWatch form and IND safety reports and assured that all SAEs followed to stabilization and resolution.

Key Duties:

- Assured that the data consistency and integrity by conducting clinical data review.
- Directed and monitored all aspects of three project operations, two phases 1 studies, and one oncology study from inception to completion within the agreed budget and time constraints.

- Organized and led serious adverse events (SAE) and SAE reporting and filing, analyzing initial and followed up SAE reports.
- Corresponded with study sponsors and federal regulatory agencies for research and document preparation for site audits as well as coordinated in tandem with nurses in a variety of diverse departments.
- Appraised and concluded IND safety reports for submission to IRB and FDA, organized SAE reconciliations and maintained files of each study.
- Submitted documents to the institutional review board (IRB) and aided with the completion of the clinical trial agreement.

2014 to 2016: Ashfield Healthcare, Mid-Atlantic Region
➲ **Clinical Oncology Specialist for Amgen Oncology**

Delivered effective support in the introduction of Neulasta ONPRO. Instructed and demonstrated on application and utilization of ONPRO, which resulted in enhancing the efficacy of nurses in the community and hospital settings. Provided effective training sessions to the oncology clinical specialists (OCS) new hire orientation on company policies, procedures, and technical instructions. Joined regional and national meetings to stay current with new developments as well as secured team members informed through the presentation of pertinent, new information, and regional/target-specific team calls. Planned and led OCS team meetings and provided exceptional training to the team members.

Key Duties:

- Formulated and maintained strong and corporate relationships with stakeholders, thought leaders, and community-based HCPs, including MDs, NPs/Pas, and nurses.
- Provided education to HCPs through presentations, in-services, and scientific exchange.
- Developed and implemented a more effective way of gathering and managing data, recognized by Amgen as "excel champion" and contributed to the creation and integration of new activity dashboards for OCS.

Research Study Experience

2014: University of Maryland School of Medicine, Baltimore, MD
➲ **Clinical Research Nurse – Cardiac Surgery**

Coordinated with the principal investigator and sub-investigators on all aspects of clinical research studies. Created and implemented patient screening and recruitment documents for clinical trials. Conformed to study sponsors and federal regulatory agencies for research and document preparation for site audits. Worked in tandem with nurses in a variety of different departments. Organized SAE reconciliation, maintained files for each study, and finished paper and electronic case report forms.

Key Duties:

- Developed and executed a new employee orientation program, submitted documents to the institutional review board (IRB), and assisted with the completion of the clinical trial agreement.
- Secured and maintained confidential database with patient information as well as executed protocol data collection and query resolution.

Key Accomplishment:

- *Decreased data queries by **99%** by answering queries within 2-3 days with explanation and documents to support response.*

2011 to 2013: Baltimore City Community College, Baltimore, MD
➲ **Clinical Instructor/Adjunct Faculty**

Key Duties:

- *Facilitated classes for medical surgical nursing clinical and lecture.*

Key Accomplishment

- *Developed tutoring program for nursing students leading to an increase in the number of nursing students passing the NCLEX and pursuing Bachelor's and Master's degrees.*

2009 to 2011: University of Maryland Medical Center, Baltimore, MD
➲ **Oncology Clinical Trial/Research Nurse Manager**

Steered and monitored ten employees and coordinated with principal investigators on all aspects of protocols in compliance with institutional review board (IRB) requirements. Performed all aspects of various operations, including analyzing consents and protocols before submission to IRB, hiring patients for eligibility, organizing patient/family education related to the clinical studies, and instructing faculty and staff on protocols. Conducted and spearheaded training programs for research nurses to increase their knowledge and represented the department at research and

protocol initiation meetings. Followed with CROs SOPs, and applicable regulations and quality standards. Ensured study start-up activities organized and completed on time, including preparation of IRB/EC submission packages and reviewing of informed consent forms. Engaged regulatory affairs/CTA hub for health authorities' submissions through the collaboration with country/cluster trial monitoring stakeholders. Coordinated with country medical and clinical trial colleagues on the implementation and delivery of assigned studies.

Key Duties

- Assured that the clinical operations for phase I-III oncology and hematology trials conducted appropriately, met key metrics, milestones, and contractual obligations by leading research nurses and monitoring activities.
- Inspected and monitored phase 1-III oncology and hematology clinical trials and responded to audits conducted by study sponsors and IRB.
- Supported to the research nurses in gathering information for annual reports and provided training on safety monitoring by collaborating with the data management department on the preparation of safety reports for DSMB.
- Developed study documents and presented safety reporting procedures to investigators and nurses monthly.

Key Accomplishment:

- Increased patient enrollment for clinical trials by **60%** from **35%** through collaboration with patient advocacy groups and churches in Metropolitan Washington, DC area.

2006 to 2008: National Institutes of Health, Bethesda, MD

➲ **Clinical Research Nurse**

Provided chemotherapy, TIL cells, and other chemotherapy products and managed phase 1-11 oncology products to the patients. Delivered exceptional and primary nursing care on assigned units to increase patient satisfaction levels. Taught patients on the side effects of chemotherapy and clinical trial products as well as conducted individual patient assessments and documented findings. Collaborated with interdisciplinary team members to deliver comprehensive and exceptional patient care. Started emergency resuscitative measures in line with the organizational protocols.

Key Duty:

- Reported and abnormal findings to the physician and provided effective care and treatment as established in the plan of care and as ordered by the physician.

Early Career

Nurse Consultant, Department on Disability Services, Washington, DC
Adjunct Faculty, Howard Community College, Columbia, Maryland

Fellowships & Awards

Maryland Higher Education Commission, Nurse Faculty Scholarship (2016 - 2018), Awarded tuition for the Ph.D. Program

Maryland Higher Education Commission, Nurse Educator Doctoral Grant (2016 – 2017), Competitive award to fund expenses related to conducting dissertation research. Dissertation topic: "A Comparative Study of Preventive Healthcare Behavior among African Immigrant Women (AIW) and African American Women (AAW): Barriers & Facilitators of Cervical Cancer Prevention"

Graduate Assistance in Areas of National Need (GAANN) Fellowship (2011 - 2014), Competitive award to assist graduate students in pursuing the highest degree available in their course study in a field designated as an area of national need.

Conferences & Presentations

University of Maryland School Nursing, Innovative Methods for Implementation Science - Volunteer, Context & Measurement Post Conference Survey (June 2013)

Barriers to clinical trial participation & tissue donation. Seventh Health Disparities Conference. New Orleans, LA. R. Baquet, MD, MPH, Jeanne Bromwell, BS, & **Vera Kuffour-Manu** (March 11, 2014).

Njathi. Overview & reflection on Malawi - Vera Kuffour-Manu, MS, RN & Dorothy Njathi. (October 22, 2012).