REMY SERGE MANZI-MUHIRE, MD, MPH
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PROFESSIONAL SUMMARY

Clinical Research Physician successful at leveraging career experience to enhance clinical trial productivity and efficiency by effectively directing operations, services and solutions while ensuring that drugs and medical devices are evaluated accurately in clinical trials. A goal-oriented healthcare professional who approaches projects with enthusiasm offering more than seven years of combined national and international experience in clinical research including four years of US experience with clinical trial management.

SKILLS

- Strong clinical judgement background with advanced application of medical terminology, pharmacology to drugs/medical devices safety.
- Comprehensive knowledge of international drug/medical device safety and pharmacovigilance principles and regulations.
- Thorough understanding of adverse event reporting and safety databases.
- Familiarity with the implementation of clinical research including complex Phase II-IV clinical trials.
- Thorough knowledge of Good Clinical Practice, ICH guidelines, HIPAA and applicable regulations.
- Strong knowledge of quality management procedures and compliance monitoring.
- Ability to develop and document risk/benefits assessment and management strategies.
- Computer savvy with proficiency in Microsoft Office, data management and statistical analysis software.
- Excellent interpersonal and communication skills with multi-tasking ability.
- Comfortable with finance, budget, and forecasting.
- Good leadership, problem-solving and time management skills.
- Demonstrates initiative and capacity to work under pressure.
- Strategic planning and people management for successful project execution.
- Full professional proficiency in French and English (S4, R4).
- Great attention to details.

SELECT EXPERIENCE

Senior Clinical Product Risk Specialist **Sep 2020 To Present**
Boston Scientific Corporation (BSC), Endoscopy Clinical, Marlborough, MA.

- Identify appropriate scope and comparative information for Clinical Evaluation Reports (CER) and drive generation or updates for those documents. Collaborate with cross-functional partners to obtain additional input to aid in clinical risk analysis.
- Conduct literature searches on gastrointestinal(GI) endoscopy products/product families to interpret and summarize harms, hazards, alternate therapies and device specific benefits from literature to support risk assessment.
- Identify the need for and/or generates risk management related documents on BSC GI endoscopy products (commercial or under development) to support internal BSC and external regulatory agency requirements.
- Serve as a liaison between Risk Management function and project team.
- Collaborate with Clinical and Research&Development to develop common cclinical deliverable criteria and strategize justification for no clinical trial or aid in development of clinical trial rationalization plan.

Clinical Research Officer **Feb 2019 To Sep 2020**
Columbia Medical University Center, Ophthalmology department, New York, NY, USA.

- Coordinated with Principal Investigators to ensure that eye diseases and vision care related clinical research activities and deliverables were executed in accordance with federal regulations, university and sponsoring agency policies and procedures.
- Performed advanced imaging procedures among patients and study participants for documenting the appearance of basic ocular structures while using cutting-edge imaging equipment that allow color fundus imaging, fluorescein angiography, fundus autofluorescence, and cross-sectional imaging of the anterior and posterior segment.

Clinical Research Consultant **Jan 2019 To Sep 2020**
Boston Scientific Corporation (BSC), Endoscopy Clinical, Marlborough, MA.

- Performed routine systematic literature reviews for endoscopy devices: Screening articles against inclusion/exclusion criteria; extracting data from articles published on PubMed, Google Scholar, EMBASE, etc; interpreting study results; preparing summaries and synthesizing literature into formal reports.
- Wrote clinical evaluation reports (CERs) and post-market surveillance documentation (PSUR, PMCF plans and reports) for CE marked endoscopy devices.
- Supported BSC Regulatory Affairs submissions for maintaining CE Mark of existing endoscopy devices in accordance with MEDDEV 2.7/1 Rev 4, MDD, AIMDD, and EU MDR 2017/745.

Clinical Research Consultant **Apr 2018 To Feb 2019**

Self-employed, Bronx, NY, USA.

- Assisted Dr Jean Claude Uwamungu, MD, cardiology fellow at Montefiore Medical Center, and his colleagues, to perform a narrative systematic review of all published case reports of Endomyocardial Fibrosis (EMF) up to 2018 worldwide.
- Led the data analysis process and the generation of a publishable manuscript which highlights the existing EMF differences and similarities. EMF trends are investigated in terms of definition, demographic, geographical distribution, diagnostics and treatment, and outcomes in patients with EMF.

Epidemiologist **Nov 2016 To Feb 2018**

Johns Hopkins School of Public Health (JHSPH), Epidemiology Department, Baltimore, MD, USA.

As a Post-doctoral fellow, I was seconded to Enda Santé International NGO based in Dakar where I:

- Reviewed and analyzed medical and scientific literature on risk/benefit of HIV prevention tools and methods, and practical application.
- Developed operational strategies for testing the introduction, acceptability, safety and use of 3000 OraQuick HIV test kits among people at risk of HIV infection in Senegal, and consequently, to determine if the promotion of self-testing increases the number of newly diagnosed PLHIV in clinic settings.
- Developed and implemented risk evaluation mitigation strategies and risk management plans, and monitored risk evaluation mitigation effectiveness related to OraQuick HIV test kits distribution.
- Led the knowledge generation and dissemination working group and worked with the JHSPH Scientific Communications team based in Baltimore to develop and execute aligned tactics for maximizing our OraQuick-related scientific communication efforts in Senegal.
- Engaged Healthcare Professionals(HCPs), Senegalese National Council Against HIV(CNLS), representatives of civil society in dialogue through workshops on peer-reviewed knowledge and standardized medical letters to ensure that providers and key populations beneficiaries have all information required to make well informed choices on the safety and appropriate use of OraQuick test kits.
- Obtained key insights from HCPs and beneficiaries about OraQuick safety, off label use and uptake experience with OraQuick HIV test kits that may influence JHSPH and Enda Sante 's strategic decision making.
- Liaised to potential areas of collaboration between HCPs and JHSPH/Enda Sante-sponsored research, clinical and research collaborations, compound transfers and vendors, and access to clinical datasets.
- Developed, tested and implemented cost-effectiveness data collection tools and analytical plans for assessing the health impact and economic outcome of three-tiers integrated stigma mitigation interventions targeting marginalized populations in Senegal (HIV Prevention 2.0 [HP2] study funded by USAID/PEPFAR).

Clinical Research Coordinator **Oct 2014 To Oct 2016**

Wills Eye Hospital, Glaucoma Research Center, Philadelphia, PA, USA.

- Managed multiple studies concurrently including Quality of Life; validation and reproducibility of the Heidelberg Edge Perimeter; a masked database of visual fields for Octopus Visual Field Machine; efficacy and safety of Bimatoprost SR (Trial, Phase III); efficacy, safety and tolerability of Trabodenoson and Latanoprost (Trial, Phase II).
- Managed all aspects of site-initiated, industry-sponsored clinical trials from start-up to close-out including clinical planning, investigator agreement, protocol development, Trial Master File (TMF) structure and preparation, enrollment of patients, follow-up visits, data acquisition, data management and assisted analysis for potential publication.
- Managed diverse clinical trials activities concurrently and ensured all safety protocols were followed.
- Authored, reviewed and submitted clinical trial documents i.e. protocols, electronic case report forms (eCRF), informed consent forms (ICF), etc. for IRB and ethics committee review.
- Administered, dispensed and collected study investigational products (IP) including drugs, medical devices etc.
- Maintained an accurate inventory for each protocol.
- Reviewed, screened electronic health records for potential study participants according to study specific inclusion and exclusion criteria.
- Performed vision screenings to study participants during their study visits
- Performed the assessment, monitoring, following-up, and reporting of safety issues associated with drugs/medical devices in trials.
- Identified and documented possible Adverse Events(AE) and Serious Adverse Events(SAE) of medical devices and drugs complaints for each study patients during study visit.
- Ensured all regulatory requirements were compiled for the safety of medical devices/drugs.
- Provided information to study patients and their families about medical devices/drug safety.
- Maintained internet-based medical devices/drug safety database and performed coding according to medical category.
- Provided accurate and timely responses to medical information inquiries from sponsors, regulators and patients.
- Trained new staff members on standard operating procedures including medical devices/drug safety as needed.
- Worked with cross-functional departments and developed standard operating procedures.
- Managed communication among study sponsors, Contract Research Organization (CRO), investigators, Vendors, patients and staffs.

Clinical Research Specialist **Jan 2014 To Jun 2014**

Thomas Jefferson University Hospitals, Center for Urban Health, Philadelphia, PA, USA.

- Performed data management and analysis using Excel and SPSS software programs for evaluating the feasibility and impact of integrating lifestyle and chronic disease management coaching with ongoing behavioral health counseling for low income, low literacy, low resourced adults who were either employed or participating in the workforce development program through Career Support Network project.

Medical Officer **Dec 2011 To Jun 2012**

Ministry of Health, Ruli District Hospital, Gakenke, North Province, Rwanda.

- Appropriately checked patients, diagnosed and treated a variety of diseases and injuries in a general setting.
- Ordered and executed diagnostic tests and analyzed diagnostic images to further investigate patient conditions.
- Administered and prescribed appropriate courses of treatments, including drugs and medical devices.
- Monitored patients' condition and progress and re-evaluated treatments as necessary.
- Performed literature review and tracked safety issues associated with medical devices and drugs among patients.
- Organized and analyzed every patient medical record for investigating side effects of medical devices/drugs.
- Provided information to patients and their families about medical devices/drug safety.
- Provided accurate and timely responses to medical information inquiries from healthcare professionals.
- Carried out campaigns for prevention and detection of diseases.
- Maintained the confidentiality of patient information as per national and international guidelines of Good Clinical Practice.

Medical Administrator **Dec 2010 To Jul 2011**

Rwanda Demobilization and Reintegration Program, Medical Rehabilitation Unit (MRU), Kigali City, Rwanda.

- Supervised decision analysis needed for better planning and implementation of medical screenings countrywide and daily management of medical & psychological needs of disabled and chronically ill veterans (both adult and child) as they reintegrated into their civilian life. This is part of World Bank's Transitional Demobilization and Reintegration Program in African Great Lakes region.
- Coordinated funding allocation among contracted service providers (i.e.: hospitals, pharmacists) for covering the cost of medical rehabilitation assistance which included surgery, endoscopy and physiotherapy procedures, provision of prostheses and mobility aids, as well as nursing care for 10,000 repatriated and disabled ex-combatants.
- Conducted rigorous analysis, design and evaluation on the reach of disabled and chronically ill veterans and outcome of the program. Then, the data generated were synthesized and built into evidence which informed the World Bank strategic investments in medical rehabilitation for vulnerable disabled veterans in Great lakes region.
- Represented MRU at the "TDRP Facility for Quality Enhancement and Innovation (FQEI)" which was a regional M&E Workshop organized by World Bank for five different programs of Disarmament, Demobilization, and Reintegration (DDR) in Africa's Great Lakes region in Nairobi, Kenya on 2-7 March 2011.

Medical Intern **Jan 2009 To Nov 2010**

Ministry of Health, Muhima District and Kanombe Military Hospitals, Kigali City, Rwanda.

- Conducted clinical evaluation with complete histories and physical examination and documented clinical findings in each patient's medical record throughout my rotations in surgery, pediatrics, obstetrics and gynecology as well as internal medicine departments.
- Attended ward rounds with consulting staff, as required, and was available to discuss every patient treatment plans.
- Performed literature review and tracked safety issues associated with medical devices/drugs among patients.
- Medically reviewed adverse events among patients for seriousness, expectedness and causality.
- Informed admitting consultants of changes either in medical condition or drug side effects of patients and of relevant action taken.
- Performed clinical procedures as requested by consultant medical staff.
- Initiated and altered in-patient prescriptions at consultant's request.
- Wrote up "to take home prescriptions" for patients and provided information to them about medical device/drug safety as required.
- Provided input for study protocol, data capture, data analysis plan, data clean-up results and analysis, and final study report for hypertension study.

Clinical Research Assistant **Aug 2010 To Oct 2010**

Center for Treatment and Research on AIDS, Malaria, Tuberculosis and other Epidemics, Kigali City, Rwanda.

- Was fully trained to investigate Adverse Event (AE) and Serious Adverse Event (SAE) of antiretroviral drugs (ARVs) among HIV infected patients during a countrywide data collection for a countrywide study entitled: "Assessment of Second Line Antiretroviral Treatment Outcomes in Rwanda 2004-2009."
- Conducted interviews, diagnosed, counseled and investigated side effects of following second line regimens: Zidovudine(AZT)/Lamivudine(3TC)/Lopinavir/Ritonavir (LPN-r); Abacavir(ABC)/Didanosine (DDI)/LPN-r; Stavudine (D4T)/3TC/LPN-r; ABC/Tenofovir (TDF)/LPN-r; TDF/3TC/LPN-r among HIV infected patients.
- Ensured data accuracy and consistency and successfully met all project milestones and timelines.

AWARDS

2012 Reed-Frost Scholarship, JHPSH, Baltimore, MD, USA.
2012 Edyth Schoenrich Student Scholarship, JHSPH, Baltimore, MD, USA.
2012 Dean's Alumni Advisory Council Scholarship, JHSPH, Baltimore, MD, USA.
2012 Global Health Bill & Melinda Gates-Keystone Symposium Travel Award, Keystone symposia, "X8 Frontiers in HIV Pathogenesis, Therapy and Eradication", Whistler, Canada.
2008 Global Health Bill and Melinda Gates-Keystone Symposium Travel Award, Keystone symposia, "E-3 Malaria symposium on Pathogenesis, Immunology and Vaccine perspectives," Alpbach, Austria.

EDUCATION

Degrees:

2016 – 2018 **Post-doctoral Fellowship in Epidemiology**
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.

2012 – 2013 **Master of Public Health (MPH)**
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.
Emphasis on Applied Epidemiology Methods, Health Systems and Health Information Systems.
Capstone paper: "Meta-evaluation of Care Group child survival projects implemented in Rwanda, Cambodia, Mozambique, Zambia and Guatemala".

2012 – 2013 **Certificate Program in Health Finance and Management**
Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA.

2004 – 2009 **Bachelor of Medicine & Surgery (MBBS, equivalent to Medical Doctor [MD] per WES evaluation report)**
National University of Rwanda, School of Medicine, Huye, South province, Rwanda.
Thesis paper: "Relationship of anthropometric indicators with blood pressure levels among undergraduate students at National University of Rwanda."

Additional Training:

2019: Columbia University Medical Center/Ophthalmology Department -> Financial Conflicts of Interest and Research for PHS researchers, How to do Human Subjects Protocols, US Food and Drug Administration(FDA)-regulated Research, HIPAA: Health Insurance Portability Accountability Act Research, Human Subjects Protection Training (includes Minors and FDA where applicable), Informed Consent Process: Assuring that it is Valid and Informed, CITI Conflict of Interest for PHS Researchers, Good Clinical Practice (GCP).

2014 & 2017: Thomas Jefferson University and Johns Hopkins University -> Initiative (CITI) Program: Good Clinical Practice, Biomedical Research and Social& behavioral research certifications. Good Laboratory Practices (GLPs), International Conference on Harmonization (ICH), Institutional Review Board (IRB) and ethics committee, FDA and HIPAA.

2015 & 2016: Wills Eye Hospital -> Blue Sky online training modules for Allergan study 192024-091: Safety reporting in clinical studies, ICH GCP Investigator training, Person IOP reading, GCP training for investigator and study staff, Safety reporting in clinical studies, Protocol highlights. Additionally, I took diagnostic equipment training, training on electronic case report form completion instructions, DIRC certification and submission procedures (Cirrus).

April 2012: Emergency Ultrasound Fellowship at Massachusetts General Hospital (MGH), Emergency department, Boston, MA, USA.

OTHER SKILLS AND ATTRIBUTES

Languages: Kinyarwanda (Native: 5S,5R), English (Fluent: 4S,4R), French (Fluent: 4S,4R), Kirundi (Intermediate: 2S,3R).

Computer Skills: ArcGIS, SPSS, STATA, EndNote, RefWorks, GapMinder, RedCap, SurveyCTO, NextGen, Epic, SurveyMonkey, Microsoft Office Suite, IRT, EDC, EMR, i2kretina, Oracle Argus, MedDRA WHO.

Link Address: http://www.linkedin.com/in/remysmanzimuhire

PUBLISHED ABSTRACTS AND MANUSCRIPTS

- Eshraghi H, Sanvicente CT, Gogte P, Waisbourd M, Lee D, **Manzi RS**, Leiby BE, Richman J, Wizov SS, Spaeth GL. Measuring Contrast Sensitivity in Specific Areas of Vision – A Meaningful Way to Assess Quality of Life and Ability to Perform Daily Activities in Glaucoma. Ophthalmic Epidemiol. 2019 Oct;26(5):301-310.

- Jean Olivier Twahirwa Rwema, **Remy Serge Manzi Muhire**, David Dowdy, Oluwasolape Olawore, Sosthenes Ketende, Carrie E. Lyons, Daouda Diouf, Fatou M. Drame, Benjamin Liestman, Karleen Coly, Cheikh Ndour, Gnilane Turpin, Souleymane Mboup, Karim Diop, Coumba Toure-Kane, Delivette Castor, Nafissatou Leye-Diouf, and Stefan Baral. Cost-effectiveness of Integrated Stigma Mitigation Interventions for Female Sex Workers in Senegal. International AIDS Conference, Netherlands, 23-27 July 2018.

- Christinah Mukandavire, Josephine Walker, Stefan Baral, Daouda Diouf, Nafissatou Leye Diouf, Fatou Drame, Safiatou Thiam, Papa Amadou Niang Diallo, Coumba Toure, Cheikh Ndour, Karleen Coly, **Remy Serge Manzi Muhire**, Sheree Schwartz, Marie-Claude Boily, Leon Danon, Erik Volz, Sharmistha Mishra, Peter Vickerman. Estimating the contribution of key populations towards spread of HIV in Dakar, Senegal. Full article published in the special issue of the Journal of the International AIDS Society 2018, 21(S5):e25126. https://onlinelibrary.wiley.com/doi/abs/10.1002/jia2.25126

- Zheng CX, Moster MR, Gogte P, Dai Y, **Muhire RS**, Waisbourd M. Implantation of trabecular micro-bypass stent using a novel "landing strip" technique. Int J Ophthalmol. 2017 May 18;10(5):738-741.

- **Muhire RS**, Myers JS, Waisbourd M, Dai Y, Myers SR, Hark LA. Factors influencing patient satisfaction in a glaucoma population. Investigative Ophthalmology & Visual Science. 2016 Sep 26;57(12):2589-.