# Francesca M. Orenge

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## EDUCATION

<b>Doctor of Philosophy in Public Health Sciences</b> <i>University of North Texas Health Science Center, Fort Worth, Texas.</i> Concentration: Epidemiology	2028 (Expected)
Master of Science in Public Health & Health Promotion Brunel University, London, UK.	September 2022
Bachelor of Medicine and Bachelor of surgery (MBChB) University of Nairobi, Kenya.	December 2015

#### PUBLICATIONS

Kapulu, M. C., **Orenge, F**., Kimani, D., Kibwana, E., Kibet, H., Mutahi, M., Datoo, M. S., Bellamy, D., Musembi, J., Ngoto, O., Rashid, H., Akinyi, S., Mwatasa, M. H., Nyamako, L., Keter, K., Gatheru, R., Mutiso, A., Musyoki, J., Mwacharo, J., ... Bejon, P. (2024). R21 malaria vaccine is protective against intradermal but not intravenous Plasmodium falciparum sporozoites in a randomized controlled human malaria infection study in Kenyan adults. *medRxiv*. <u>https://doi.org/10.1101/2024.08.06.24311495</u>

# PROFESSIONAL EXPERIENCE

# **OCT 2021–JUL 2024: Research medical officer-in-Charge**, KEMRI- Wellcome Trust Research Program (KWTRP), Kilifi, Kenya.

Clinical work experience:

- Provided clinical oversight as a medical lead for the team by providing medical guidance in terms of treatment guidelines and current clinical best practice at the clinical trial sites and the affiliate hospital (Kilifi County Hospital).
- Directly provided clinical care to hospital patients and clinical trial participants thereby gaining experience in managing various conditions that included diabetes and cardiovascular diseases.
- Actively participated in Continuous Medical Education activities such as medical seminars, journal club presentations, medical webinars to keep up with current knowledge and guidelines in various disease states. Medical advisor and Scientific communication functions:
- Cultivated useful relationships with both internal and external collaborators through transparent, timely and effective communication thus increasing stakeholder satisfaction.
- Acted as the medical/scientific liaison of the team by serving as a point of contact for all medical enquiries and scientific matters throughout the life cycle of the clinical trials right from proposal writing to results dissemination to various audiences including medical experts in the Kenya Medica Association (KMA).
- Provided scientific support by reviewing medical educational and promotional clinical trial materials for scientific accuracy and relevance.
- Oversaw the clinical safety of trial participants by providing support and guidance on all pharmacovigilance matters and providing medical information to research volunteers as required.

- Trained 20-30 study team members on the various study protocol explaining key scientific concepts attaining 100% preparedness of the team before study conduct.
- Brainstormed with the Principal Investigator (PI) and provided technical guidance on proposal writing, study design and developed study protocols and study related documents (MOP, SOPs, SSP, CRF and ICF) subsequently enhancing study set-up and start-up.
- Co-authored and reviewed documents such as manuscripts (currently undergoing co-author reviews before submission), abstracts for conferences, power point presentations for kick-off meetings and other stakeholder meetings.

Project management experience:

- Designed project timelines, proposed study budgets, tracked project progress and implemented quality monitoring tools yielding high quality project outcomes.
- Supervised and coached a team of 15 clinical trial staff, delegating work to complete project work packages on-time and on-budget demonstrating high-level management skills.
- Steered regular project team meetings/conference calls and conducted follow-up of action items which streamlined workflow processes and led to the achievement of project deliverables on time and within budget.
- Secured local and international IRB/IEC and regulatory approvals for the studies through facilitating preparation of submission packages.
- Undertook risk assessment for the projects as well as mapped out mitigation plans and resolved any issues in liaison with the PI.
- Structured various plans for conduct of the study i.e. plans for community engagement, recruitment, quality assurance, and clinical monitoring which led to optimized project quality and adherence to study protocol, GCP guidelines ethical and regulatory requirements.

#### **NOV 2022- JUL 2024: Part-time scientific and medical manuscript editor** at TOPEDIT sci services. Responsibilities:

•Conducted scientific fact-checking and different levels of editing (copy editing, line/deep editing, developmental/ substantive editing) on scientific manuscripts in the specific fields of Infectious Diseases, Internal Medicine, Paediatrics, epidemiology, Health Economics, Health Policy, Global Public Health, health promotion, and clinical research (Drug trials, Vaccine trials, Human Infection Studies, and Challenge studies).

•Made suggestions for improvement to the structure and content of the title, abstract, introduction, methods, results, discussion, charts, and references sections to increase chances of publication by meeting the requirements of the intended journal.

**FEB 2019- NOV 2019: Lead site investigator/study physician -** Kenya Medical Research Institute (KEMRI) – Centre for Clinical Research (CCR) and Drugs for Neglected Diseases Initiative (DNDi). Responsibilities:

•Guided the study site team in provision of medical care (including nursing and pharmacy team) in compliance with all laid down medical care and research protocol guidelines through mentorship and coaching.

•Developed Standard Operating Procedures for the study and introduced site-specific quality control measures to ensure optimal adherence to study protocol, regulations, and set policies.

•Streamlined workflow processes and chaired weekly team meetings, clinical skills training meetings and update meetings as required.

•Initiated activities regarding community engagement and sensitization and field work on visceral leishmaniasis and active case search by the field workers.

Monitored, assessed, documented, and reported events regarding safety: AEs and SAEs of study participants.
Communicated with various stakeholders; sponsor team, Scientific and Ethics Review Unit (SERU) – KEMRI, Pharmacy and Poisons Board and county government officials.

**Feb 2016- Dec 2018: Medical office**r - Iten County Hospital, Iten town and international rescue committee at the Kakuma refugee camp.

Responsibilities: General Physician responsibilities.

Professional development courses/training

- ✓ Human Subjects protection CITI (2024)
- ✓ Grant writing African Research Excellence Fund (AREF) Nov 2023
- ✓ Data analysis using R statistical Software Cousera
- ✓ Budgeting and scheduling Projects The University of California, Irvine extension (Sept 2019)
- ✓ Project Management The University of California, Irvine extension (Aug 2019)
- ✓ Epidemiology: The basic science of Public Health -The University of North Carolina, (Aug 2019)
- ✓ Research Ethics Training Curriculum FHI 360 (Jan 2019 and 2021)
- ✓ ICH Good Clinical Practice E6 (R2) -The Global Health Network (Nov 2018 and Jan 2022)
- ✓ Introduction to data management The Global Health Network (Nov 2018)
- ✓ Introduction to clinical research The Global Health Network (Nov 2018)
- ✓ Becoming an Effective leader Humanitarian leadership academy (Oct 2018)

### Membership, Affiliations, and other professional activities.

- 1. A member of the KEMRI -Wellcome Trust Communications and Consent Committee (CCC) I reviewed research studies information sharing sheets and informed consent forms as well as other communication materials (2023-2024)
- 2. A member of the KEMRI -Wellcome Trust Centre Scientific Committee (CSC) I reviewed research concept notes, new research protocols and protocol amendments (2021-2024).