Centre for Microbiology Research

KEMRI- RCTP

VACANCY ANNOUNCEMENT

Opening Date: 20th April, 2022

Background Information:

Sanofi study: A parallel-group, Phase III, multi-stage, modified double-blind, multi-armed study to assess the efficacy, safety, and immunogenicity of two SARS-CoV-2 Adjuvanted Recombinant Protein Vaccines (monovalent and bivalent) for prevention against COVID-19 in adults 18 years of age and older.

We have the below vacancies in the SANOFI study.

1. Position: Study Pharmacist (1 Position) K MR 6 Vacancy No. FN-001-04-2022

Reports to: Study Doctor

Location: Kisumu

Duration: 1 Year Renewable Contract as per KEMRI Scheme of Service. The first 3 months is a probation period

Qualifications:

- Bachelor of Pharmacy Degree from a recognized University.
- Registered with the pharmacy and poison board
- Masters in Public Health will be an added advantage**.**

Duties and Responsibilities:

- Management of regulatory affairs regarding pharmacy and enhancing communication between pharmacy and local PPB and the site.
- Monitor drugs and other medical supplies levels and initiate the procurement process.
- Take inventory and track medication and supply orders as well as expiries. Keep records of all drug stocks ordered, drugs issued to clients and stocks remaining
- Participate in the review, planning and implementation of clinical trials. This will include the evaluation of study design, feasibility, pharmaceutical regulatory requirements, and identifying solutions for pharmaceutical and logistical problems that may impede the conduct of a study
- Develop the text for the study product section of the protocols in cooperation with members of the protocol team and the pharmaceutical manufacturers for existing pharmaceutical products as well as new chemical entities and modalities. This includes researching and analyzing background material from Investigator's Brochures, prescribing information, and literature reviews.
- Advise the study team and leadership regarding pharmacy aspects of proposed studies
- Develop protocol specific trainings for site pharmacists and clinic staff utilizing web-based systems, software, or other tools (ie., power point presentation).
- Provide leadership in collaboration Project Managers for developing study-specific blind labeling and packaging plan and strategies.
- Write and review Study Specific Pharmacy Manuals in collaboration with Project Managers.
- Ensure that pharmaceutical concerns are raised during meetings are addressed in a timely manner

- Advise the protocol team regarding pharmaceutical issues relating to PPB standards, FDA and other Health Authorities regulations, State and in-country requirements.
- Evaluate the protocol and provide leadership with estimates of study product needs and or cost based on factors such as sample size, dose, formulation, strength, rate of accrual, and duration.
- Perform calculations for study product dilutions and aliquots and for compounding pharmaceutical preparations.
- Generate Study Product Request Letter/ Email for study-specific and division leadership's review and approval.
- Provide pharmaceutical expertise during protocol conduct on pharmacy queries, product management issues, product availability and appropriate recommendations.
- Obtain information about existing infrastructure and processes to use to evaluate pharmacy personnel and infrastructure capacity the Clinical Research Site,
- Evaluate and finalize all temperature excursions that occur during shipment and at Research Pharmacy Sites in collaboration with PI and study coordinators
- Receive and process product complaints with or without AES/SAEs from research site pharmacies.
- Write/draft Standard Operating Procedures (SOPs) related to Pharmaceutical Services and participate in SOP review committees as needed.
- Utilize pharmacy practice experience and pharmaceutical expertise in the design, review and revision of DAIT Pharmacy documents.
- Participate in meetings, face-to-face protocol development meetings, and protocol team meetings as a pharmaceutical subject matter expert.
- Review pharmacy monitoring assessment reports and provide input regarding pharmacy and protocol prioritization for Clinical Site Monitoring plan as needed.
- Order, receive, ship study products and maintain chain of custody of Investigational Products (Ips) purchased or received by the trial site(s).
- Ensure proper storage conditions for IPs including maintaining pharmacy temperature and humidity logs
- Update the database of IPs and other pharmacy products on a monthly basis. Ensuring accurate and timely records of dispensed drugs and study products on the pharmacy logs and in the accountability logs and Database.
- Administer respective Case Report Forms (CRFs)
- Carrying out QA/QC of study CRFs and source docs and resolve queries that may arise.
- Dispensing drugs and Study products to participants.
- Counselling participants on adherence to study products
- Participants Randomization process in liaison with the data and clinic teams and ensure blinding.
- Processing study products destruction documents and taking part in actual destruction process.
- Training other staff on pharmacy protocol based procedures.
- Perform projection and orders of the required drugs in liaison with the study clinicians and account for their use
- Perform stock checks and share out to the prescriber.
- Prepare and dispense prescribed medications and pharmaceutical preparations according to participants' prescription.
- Provide advice for non-prescription medications.
- Establish and maintain good relationships with participants to foster study retention.
- Prepare weekly and monthly progress reports of personal study activities
- Closely work with other staff members to ensure the success of the study

Other Required Skills

- Commitment to integrity and high quality performance
- Good interpersonal skills and ability to work in a team
- Keen and attentive to detail
- Ability to follow instructions and procedures
- Articulate in both verbal and written communication in English and Swahili.
- Counselling skills
- Good track of record keeping
- Some store keeping skills
- Computer literacy

2. Position: Pharmaceutical Technologist (2 Positions) K MR 7 Vacancy No. FN-002-04-2022

Reports to: **Study Pharmacist**

Location: **Kisumu**

Duration: **1 Year Renewable Contract as per KEMRI Scheme of Service. The first 3 months is a probation period**

Qualifications

- Diploma in Pharmaceutical Technology
- Registered with the pharmacy and poison board

Duties and Responsibilities

- Administer respective Case Report Forms (CRFs)
- Carrying out QA/QC of study CRFs and source docs and resolve queries that may arise.
- Dispensing drugs and Study products to participants.
- Ensure prescription drugs are available for dispensing to participants
- Maintaining pharmacy temperature and humidity logs
- Counselling participants on adherence to study products
- Participants Randomization process in liaison with the data and clinic teams.
- Ensuring accurate and timely records of dispensed drugs and study products on the pharmacy logs and in the accountability logs and Database.
- Prepare and dispense prescribed medications and pharmaceutical preparations according to participants' prescription.
- Establish and maintain good relationships with participants to foster study retention.
- Closely work with other staff members to ensure the success of the study

Other Required Skill

- Commitment to integrity and high-quality performance
- Good interpersonal skills and ability to work in a team
- Keen and attentive to detail
- Ability to follow instructions and procedures
- Articulate in both verbal and written communication in English and Swahili.
- Counselling skills
- Filing and store management.

How to Apply

a) All applicants must meet each selection criteria detailed in the minimum requirements.
b) Must include a current CV with names of at least three referees.
c) Must include copies of academic and professional certificates.

A duly signed application letter indicating the vacancy reference with copies of documents listed above should be sent to: **hrrctp@kemri-rctp.org** not later than 10th May, 2022.

KEMRI IS AN EQUAL OPPORTUNITY EMPLOYER COMMITED TO DIVERSITY;PERSONS WITH DISABILITY, WOMEN, YOUTH AND THOSE FROM MARGINALIZED AREAS ARE ENCOURAGED TO APPLY.

Only short-listed candidates will be contacte