Project Title: The proportion, rate and causes of screen failures in preventive HIV vaccine clinical trials in South Africa

Preferred Scholar On-Site Project Dates: Short-term Project, Onsite, 8-10 weeks (May 2024-July 2024)

Project Site: Durban, South Africa (HIV and Other Infectious Diseases Research Unit (HIDRU), South African Medical Research Council (SAMRC))

Project Overview:

The Isipingo clinical research site (CRS) is one of six CRSs at the HIV and Other Infectious Diseases Research Unit (HIDRU), South African Medical Research Council (SAMRC), Durban, South Africa. HIDRU conducts research in HIV prevention, COVID-19, Tuberculosis and Sexually Transmitted Infections (STIs). The Isipingo CRS has experience in all clinical trial phases, from phase I to phase IV. The Isipingo CRS has been implementing HIV Vaccine Trials Network (HVTN) studies since 2014. The scholar will have the opportunity to spend time with the study team to understand the recruitment processes conducted as Isipingo CRS for HVTN studies. The scholar will have access to participant screening visit binders and Medidata to extract data. Further, the scholar will have exposure to primary and secondary data collection, and quantitative research methods and analysis. The scholar will have the opportunity to spend time with the statistics team to increase knowledge and acquire basic statistical skills.

Project Summary:

The aim of this project is to identify and describe barriers, facilitators, and predictors of recruitment in HVTN studies conducted at the Isipingo CRS since 2014 to 2022. The project collects both primary and secondary data. Primary data will be collected from the participant binders- locators and the checklists. Secondary data will be collected from Medidata-electronic case report forms (demographics and screen outcome), and HVTN SCHARP study-specific screening and enrollment reports. The data will be analyzed by descriptive and analytical statistical methods to identify predictors of successful recruitment. Two hypotheses will be tested 1) The screen failures due to HIV and pregnancy in phase I and III studies are higher than the screen failures due to abnormal laboratory findings in phase I and III studies implemented at Isipingo and 2) There is a higher percentage of newly diagnosed HIV cases and pregnancies in women in the age group 18-24 years of age than women in the age group older than 25 and above in phase I and III studies implemented at Isipingo CRS.

Regulatory requirements for the project and plans for completing them:

The protocol will be submitted to the SAMRC scientific review committee as a pre-requisite for Ethics Committee (EC) submission. With the scientific review approval, the proposal will be submitted to EC for approval. The entire process from scientific review to EC approval takes approximately three months. This process will begin in February 2024. The scholar will require Good Clinical Practice (GCP) face-to-face training and online DAIDS GCP and Human Subject Participant (HSP) training.

Expected Deliverables:

The scholar will be expected to complete Redcap training for data management. He/she will be involved in data capturing, data cleaning and data quality control. The scholar will be involved in both descriptive and analytical data analysis including summary statistics for both numerical and categorical data; Chi-square analysis to identify statistically significant variables; univariate analysis using odds ratio as a measure of association; and finally multivariate analysis to identify predictors. The scholar is expected to lead the publications but will be supervised and assisted by the project team. Onsite training will be conducted by various staff to allow the scholar to learn about implementation and operational challenges of clinical trials. The scholar is expected to become familiar with all procedures in a clinical trial from the screening, enrollment, follow-up visits, informed consent process, co-enrollment procedures, protocol procedures and quality control and assurance. The scholar will complete DAIDS courses to understand concepts in clinical trials, including GCP, HSP and introduction to ethics in research. Quantitative data collection will be conducted over 8-10 weeks onsite. Weekly off-site virtual meetings will be scheduled for off-site data analysis and write-up for oral presentation at the HVTN Full Group Meeting in 2025 and a manuscript for publication. Microsoft Teams will be used as a platform to share documents, schedule meetings and work on live documents.

Project Contact Person(s) (Name, Email):

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