**MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES**

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**STUDY REPORT**

**Title: Assessment of the challenges encountered in implementing vaccine clinical trial methodologies in Tanzania**

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**Introduction**: An exploratory qualitative study design involving key informant interview of personnel responsible for the conduct of vaccine trial and the focus group discussions with trial participants is on-going in Tanzania. The study includes on-going vaccine clinical trials at Muhimbili University of Health and Allied Sciences (MUHAS) and Ifakara Health Institute (IHI); HIV vaccine, malaria vaccine, and Tuberculosis vaccine clinical trials. Also, the clinical trial regulators and ethical committees are included in the study.

**Progress made:** Key informant interviews have been conducted with vaccine investigators of TB and HIV vaccine trials; the investigators were medical doctors, pharmacists and nurses. Also key informants from regulatory authority have been interviewed.Interviewers that involve ethical committees as well as from Malaria vaccine is scheduled to be conducted in February, 2021.

**Challenges that have caused delay:** Delay in getting ethical approval. It took two months for the ethical clearance to be issued. In addition, the MUHAS and UoL signed the agreement in August, 2020 which was two months late from the planned date of study commencement. Also, we received 80% of grant on 4th November, 2020 which was needed for payment of research assistants for data collection. Delay in signing contract as well as disbursement of fund affected the time of starting data collection which was planned to start from June, 2020 to March, 2021 (10 months’ period).

**Issues or challenges which are new or ongoing which will impact the project:** Slow rate of recruitment because we work based on appointment, availability and convenience. We are sometimes being scheduled for more than 2 weeks. This have affected the estimated time of study completion. Coordinators of TB and HIV vaccine trials refused to provide contact and list of trial participants due to fear of breach of confidentiality, so they may not be included in our study as proposed. The study will lack experience from TB and HIV trial participants and therefore, the findings will rely on experiences from investigators, regulators and ethical committees.

**Mitigation measures**

1. Making many appointments as much as possible so as to compensate the time between long appointments.
2. Solicit permission from trial coordinator to involve trial participants from malaria vaccine.
3. Accepting that participants from TB and HIV will not be included in the study.
4. Extend time of study completion from March to April, 2021.

**Abstract**

Effective vaccine use is a global approach expected to eliminate infectious diseases. Recent developments have been made to produce a number of vaccines which are in various phases of clinical trial such as Tuberculosis (TB), malaria and human immunodeficiency virus (HIV) vaccines. Despite of these, only few vaccine clinical trials are conducted in low and middle income countries including sub-Saharan Africa. An exploratory qualitative study is ongoing in Tanzania to explore the challenges encountered by vaccine trial investigators when implementing vaccine trial methodologies. The key informant interview that involves, trial coordinators, principal investigators, pharmacists, nurses and laboratory scientists is being conducted to explore their experiences on the conduct of vaccine trials in low middle income countries like Tanzania. Also, key informants from clinical trial regulators and ethical committees are involved. Similarly, trial participants are involved in the focus group discussion to explore the challenges they encounter for their involvement in vaccine clinical trial. Currently, the key informants from TB and HIV vaccine trial and clinical trial regulators have been interviewed. Recruitment of key informants from malaria vaccine trial and ethical committee is still ongoing.