

**Insert Institutional LOGOs (if applicable)**

**STUDY PROGRESS REPORT**

**[PROTOCOL TITLE]**

**Protocol RNEC Reference Number**

**Principal Investigator:**

- Insert the Name of the Principal Investigator and his/her affiliation(s)

**Co-Principal Investigator(s):**

- Insert Names of all Co-Investigators and their affiliations

**Co-Investigator(s):**

- Insert names of all Co-Investigators and their affiliations

**Date of Report**

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## **ACRONYMS AND ABBREVIATIONS**

**ABC:**

**RNEC:** Rwanda National Research Ethics Committee

## **1. INTRODUCTION**

Insert a brief and concise introduction of the study.

## **2. RATIONALE**

Provide a rationale for conducting the study and why it should be performed in Rwanda.

## **3. OBJECTIVE OF THE TRIAL**

Insert here the general aim of the protocol study. Include the primary objective and secondary objectives.

### **3.1. Specific Objective(s):**

Include here the primary objective.

## **4. PLANNED STUDY TIMELINE**

Describe the planned time frame.

## **5. STUDY PROGRESS**

### **5.1. Progress report and recruitment summary**

Provide a brief progress report here. Describe all activities, challenges, including participant recruitment and follow-ups. Describe the current stage of the study. Briefly summarize activities conducted during the past approval period.

### **5.2. Study site(s) and Participant Recruitment**

Describe the current study site(s) and provide recruitment numbers by site. Explain any recruitment challenges or delays

### **5.3. Participants' withdrawal and lost to follow-up**

Provide reason(s) if any withdrawn participants or lost to follow-up registered (if any)

### **5.4. Reasons for study extension**

Describe why you are applying for an extension or re-approval:

## **6. Protocol Deviations, Adverse Events, and Unanticipated Problems**

Describe the protocol adherence status. If any protocol deviations or violations have occurred, explain and attach reports. If any adverse events or unanticipated problems have occurred, provide a summary and attach reports. If there have been any adverse events (AEs) or serious adverse

events (SAEs), please provide the date, description, event description, severity, outcome, and whether it was reported to RNEC using the table below and attach full reports.

Date	Event Description	Severity	Outcome	Reported to RNEC (Date)
Click or tap to enter a date.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap to enter a date.

## 7. Risk and Benefits Reassessment

Briefly describe the risks to participants. If participant risk has increased based on study experience to date, describe the nature of the risk and mitigation measures. If any preliminary results or benefits have emerged, briefly describe. If any findings have altered the original risk-benefit balance, please explain.

## 8. Informed Consent and Vulnerable Populations

Describe the informed consent process. If the consent documents have been revised since the last approval, explain the changes and attach the updated versions. If any participants have raised complaints or concerns regarding consent or participation, please explain. If the study involves vulnerable populations, specify and confirm that safeguards remain in place.

## 9. Data Protection and Confidentiality

If there have been any issues of maintaining confidentiality and data protection measures as approved, please explain. If there have been any data breaches or loss of study data, please describe corrective measures.

## 10. Data Safety Monitoring Board (DSMB) Report (if applicable)

If there have been any Safety Monitoring Board (DSMB) Reports, please summarize the recommendations. Please include details of outcomes and conclusions.

## 11. Amendments Since Last Approval

If there have been any approved amendments since the last renewal, list approval dates and a brief description of the amendments using the table below:

Amendment Date	Description	RNEC Approval Date
Click or tap to enter a date.	Click or tap here to enter text.	Click or tap to enter a date.

## **12. Preliminary Findings, Publications or Dissemination**

If any results have been published or presented, please list publications, abstracts, or presentations. Give details of any publications and send copies when available

## **13. Plans for the Next Approval Period**

Briefly describe planned activities for the coming year

## 14. Annexes