Quality Medicines for Malawi

CLINICAL TRIAL ANNUAL PROGRESS REPORTING FORM FOR INVESTIGATORS

Preamble:
In line with section 77 of PMRA Act 2019, PMRA is mandated to monitor approved clinical trials. The purpose of monitoring is to verify that the rights and well-being of the participants are protected and the conduct of the trial is in compliance with the currently approved protocol/amendment(s), GCP and the applicable regulatory requirements.

Instructions:

1 All sections of this form must be completed in typescript and submitted by the Principal Investigator together with accompanying documents to the Director General, PMRA at info@pmra.mw. Both hard and soft copies must be submitted.

2 For questions with Yes/No options please indicate answer in bold type.

SECTION A. ADMINISTRATIVE INFORMATION				
PMRA Reference Number:	Actual date of commencement (at the Study site):	Study duration 20…….to 20……	Protocol Version Number	Are you still within the initially applied study duration? Yes ☐ No ☐ If **No**, please apply for extension of study duration
Study Title				
Study Sites				
Reporting Period	From …… To ……			
Institution:				
	Name:			

Principal investigator	Address:	Phone Email
Contact Person: (If applicable)	Name:	
	Address:	Phone Email

SECTION B: REGULATORY COMPLIANCE	
i. Number of GCP monitoring visits conducted (attach *monitors reports*)	……..
ii. Number of GCP audits conducted (attach *audit reports*)	……..
iii. Attach a copy of the following documents ☐Clinical trial insurance certificate *(mandatory)* ☐Clinical trial indemnity form (*mandatory)* ☐IND approval *(if applicable)*	

SECTION C. STUDY STATUS (check one category only)
☐Enrolment has not begun ☐Actively enrolling subjects ☐Enrolment closed on: (insert date): subjects are receiving treatment/intervention ☐Enrolment closed on: (insert date) subjects are in follow up only ☐Analyzing data ☐Data analysis completed

SECTION C. PROGRESS REPORT (since last review) *IT IS MANDATORY TO COMPLETE ALL THE RELEVANT FIELDS IN THIS SECTION*	
i. Total number of subjects consented and screened	
ii. Total number of subjects consented and screened who are eligible for the study.	
iii. Number of subjects to which the investigational product has been administered	
iv. Number of subjects left to be enrolled in the coming months (years)	
v. Please report the number of participants in Malawi in the following categories: *(Total should add up)*	
• Currently active in study • Follow-up data collection only • Completed intervention and any follow-up • Lost to follow-up	
Adverse Events, Protocol deviations/violations, Complications, Withdrawals	
vi. Number of participants who have discontinued the study: • By investigator • Voluntarily • Due to SAE	

vii.	Have there been any Individual Case Safety Reports (ICSRs)[1] in the study? Number of Adverse events (AE's) Number of Serious Adverse Events' (SAEs) Number of Adverse drug reactions (ADR's) Number of Suspected Unexpected Serious Adverse Reactions (SUSAR) *(Attach line list of all ICSR's documented for the reporting period stating nature of AE, grading, severity, date of awareness, date of reporting, relationship to IMP, and outcome)*	☐Yes ☐ No ……. ……. ……. …….
viii.	In the past approval period, did any protocol deviations / violations occur? Total number of deviations/violations: …….. (Attach line list of deviations/violations documented and the Corrective Actions and Preventive Actions (CAPA) taken for the reporting period)	☐Yes ☐ No
ix.	Have any substantial amendments been made to the protocol since the last reporting period. Total number of substantial amendments submitted to PMRA…….. (Attach line list of amendments submitted for the reporting period). *('**Substantial amendment**' means any change to any aspect of the clinical trial which is made after notification of a decision and which is likely to have a substantial impact on the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial)*	☐Yes ☐ No
x.	How many Data Safety Monitoring Board /Data Monitoring Committee meetings were conducted in the reporting period...? *(if applicable)*	
xi.	Have DSMB meeting been conducted as per the expected schedule of meetings over the course of the trial enumerated in the protocol? ☐ Yes ☐ No. If No, explain why. *(Attach all DSMB reports to date for the reporting period).*	
xii.	Based on your knowledge of the events for this study, was there a significant increase in the number of severe adverse events or adverse outcome events compared to the baseline estimates? ***If yes, explain* why and CAPA taken.**	☐Yes ☐ No
Investigational Medicinal Product (IMP) status		
xiii.	In the reporting period how many products were imported into the country……?	
xiv.	Have any IMP's been destroyed in the reporting period? *(Attach destruction certificate/details)*	
xv.	Have there been any quality issues and/or notification of product recalls with the IMP? If yes, describe below.	
xvi.	Date for the end of study ……..	
xvii.	Date for the final study report ……..	

[1] Individual Case safety report (ICSR) is the umbrella term for Adverse events (AE), Serious Adverse Events (SAE's), Adverse events following immunization (AEFI's) and Adverse drug reactions (ADR's)

SECTION D: OTHERS
Are there any other developments in the trial that you wish to report to PMRA? Are there any regulatory issues on which further advice is required?

SECTION E: COMMENTS (if any)

SECTION F: DECLARATION	
Signature of Principle Investigator/Sponsor:	
Name of Principle Investigator/Sponsor:	
Date:	