Medicines Control Authority of Zimbabwe

PVF 76

PHARMACOVIGILANCE AND CLINICAL TRIALS DIVISION

CLINICAL TRIAL ANNUAL PROGRESS REPORTING FORM FOR INVESTIGATORS

Preamble:
In line with section 23 of MASCA Chapter 15:03, MCAZ 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 **electronically.**
2. The form together with accompanying documents are to submitted to MCAZ at 106 Baines Avenue, Harare or via email at mcaz@mcaz.co.zw by the **31st of January annually.**

SECTION A. ADMINISTRATIVE INFORMATION				
MCAZ 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:				
Principal investigator	Name:			
	Address: Phone			

	Email
Contact Person:	Name:
(If applicable)	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)* ☐MCAZ Premises license for the Research Pharmacy ☐IND approval *(if applicable)*	

SECTION C. STUDY SATUS (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 Zimbabwe 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 Adverse events following immunization (AEFI's) *(Attach line list of all ICSR's documented for the reporting period)*	☐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 taken for the reporting period)	☐Yes ☐ No
ix.	Have there been any changes to the protocol since the last reporting period. Total number of amendments submitted to MCAZ……. (Attach line list of amendments submitted for the reporting period)	☐Yes ☐ No
x.	How many Data Safety Monitoring Board /Data Monitoring Committee meetings were conducted in the reporting period...? *(if applicable)* Have all DSMB reports been submitted to the MCAZ? ☐Yes ☐ No	
xi.	Based on your knowledge of the events for this study, was there a significant increase in risk to participants? ***If yes, explain* why and corrective action taken**	☐Yes ☐ No
	Investigational Medicinal Product (IMP) status	
xii.	In the reporting period how many products were imported into the country……? Total number of Section 75 applications submitted to MCAZ……. (Attach line list of Section 75 applications documented for the reporting period)	

[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)

xiii. Have any IMP's been destroyed in the reporting period?
(Attach destruction log/details)

xiv. Have there been any quality issues and/or notification of product recalls with the IMP? If yes, describe below.

xv. Date for the end of study ……..

xvi. Date for the final study report ……..

SECTION D: COMMENTS, (If any)

……..
Signature of Principal Investigator

……..
Date