MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

SIX MONTHLY PROGRESS REPORT FORM FOR CLINICAL TRIALS

INSTRUCTIONS

1. This form is to be completed six-monthly from the date of approval of the clinical trial by the Medicines Control Council (MCC).

2. The applicant/sponsor must complete Parts A and B.

3. Part A is specifically for the study participants in South Africa.

4. Part B is an overall safety line listing for the study in South Africa and worldwide and includes all severe adverse events and suspected unexpected severe adverse reactions for all participants in this study.

5. *Note:* Protocol Deviations must be reported separately to MCC.

6. Progress reports are to be submitted to the following address:

   Registrar of Medicines
   Medicines Control Council
   Clinical Trials Unit
   Private Bag X828
   Pretoria

CLINICAL TRIAL SIX MONTHLY PROGRESS REPORT

PART A: STUDY OVERVIEW SOUTH AFRICA	
1 MCC Database tracking number	
2 Study Title	
3 Protocol number	
4 *Details of Sponsor / Applicant:*	
4.1 Name of Sponsor	
4.2 Name of Applicant	
4.3 Contact Person	
4.3.1 Telephone number	
4.3.2 Fax number	
4.3.3 Cell-phone number	
4.3.4 E-mail address	
5 List of all active trial sites and Principal Investigators (PIs)	
6 *Trial Information:*	
6.1 Date of approval of study	
6.2 Date of commencement of the study	
6.3 Treatment hold (if applicable)	
6.4 Expected date of completion	
7 Number of participants in the trial:	
7.1 Enrolled	
7.2 Randomised	
7.3 Withdrawn	
7.4 Treatment completed	
7.5 Lost to follow-up	
7.6 Deaths	
8 Applicant/Sponsor summary of progress to date	
9 Safety Committee Interim analysis recommendations	

PART B: OVERALL SAFETY LINE LISTING		
10 Safety Line Listing of all Serious Adverse Events (SAEs) for all participants per site in this study		
SAE	**Causality**	**Outcome**
Site 1: (name of site)		

Site 2: (name of site)		
Site 3: (name of site)		
SAEs Outside South Africa		

11 National Principal Investigator report on other safety concerns	**(Provide detailed text here)**

12 Line Listing of all major protocol violations at the site:

Protocol *Violation* is any change, divergence, or departure from the study design or procedures defined in the protocol that might significantly affect a participants' safety, and well-being and/or the reliability of the study data

Protocol *Deviation* is accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or does not have a significant effect on the participants, safety or well-being; and/or the reliability of the study data.

Note: Protocol Deviations must be reported separately to MCC.

Major Protocol Violations	**Comment**
Site 1: (name of site)	

Site 2: (name of site)	
Site 3: (name of site)	
Signature of National Principal Investigator	**Date**
Signature of Applicant/Sponsor	**Date**

FOR MCC USE ONLY:

Comments:

Action: ☐ **Continue Trial**

☐ **Further information required from Applicant / Sponsor**

☐ **Refer to Clinical Trials Committee and / or Inspectorate**

Reviewed by: ..... **Date:** .....

Signature: .....

UPDATE HISTORY

Date	Reason for Update	Version & Publication
November 2017	First version published for implementation	Version 1, January 2018