



SAHPRA
South African
Health Products
Regulatory Authority

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 South African Health Products Regulatory Authority (SAHPRA).
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 any other issues of special concern outside South Africa) and includes all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARS) for all participants in this study.
5. *Note:* Protocol Deviations must be reported separately, six-monthly to SAHPRA. Protocol deviations are not part of the report but should be submitted as a separate communication at the same time as this report.
6. Progress reports and protocol deviations are to be submitted to the following address:

Chief Executive Officer
South African Health Products Regulatory Authority
Clinical Trials Unit
Private Bag X828
Pretoria

CLINICAL TRIAL SIX-MONTHLY PROGRESS REPORT

PART A: STUDY OVERVIEW SOUTH AFRICA	
1	SAHPRA Database tracking number
2	Study Title
3	Protocol number
4	<i>Details of Sponsor / Applicant:</i>
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, address and Principal Investigators (PIs)
6	<i>Trial Information:</i>
6.1	Date of approval of study
6.2	Treatment hold (if applicable) with reasons (start date and stop date of hold should be included)
6.3	Expected date of completion
7	<i>Number of participants in the trial (per site), (this section should be accumulative):</i>
7.1	Screened (signed consent)
7.2	Randomised
7.3	Withdrawn from treatment (continue in follow up), with reasons
7.4	Withdrawn from study (early termination), with reasons
7.5	Study completed
7.6	Lost to follow-up
7.7	Deaths
8	Applicant/Sponsor comment on progress to date
9	Summary Data Safety Monitoring Board or Safety Committee recommendations

PART B: OVERALL SAFETY LINE LISTING		
10 Safety Line Listing of all Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse Reactions (SUSARS) for all participants per site in this study in South Africa <i>Note: Detailed Site Specific Line listing may be submitted as an attachment (should not be accumulative) as per Safety Reporting guideline</i>		
SAEs and SUSARS	Relationship to study medicine (investigator's opinion)	Outcome(s)
Site 1: (name of site)		
e.g. Pneumonitis (7 patients)	Possible (2) Probable (1) Definite (2) Unrelated (2) unknown (0)	7 patients recovered 2 still treated
Site 2: (name of site)		
Site 3: (name of site)		
Any safety issues of special concern outside South Africa		
11 Line Listing of all critical and major protocol violations at the site: Protocol <i>Violation</i> is any change, divergence, or departure from the study design or procedures defined in the protocol that might significantly affect 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: South African Site Specific Line Listing of all major protocol violations may be submitted as an attachment

Site specific Protocol Deviations must be reported separately to SAHPRA, six-monthly.

Critical and Major Protocol Violations	Resolution/Action taken
Site 1: (name of site)	
Site 2: (name of site)	
Site 3: (name of site)	
12 National Principal Investigator comment on other major safety concerns (this should include information impacting on the risk-benefit profile, including changes in nature, severity or frequency of risk factors, etc.)	(Provide detailed text here)
Signature of National Principal Investigator	Date
Signature of Applicant/Sponsor	Date

FOR SAHPRA 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
May 2018	Changes to sections 1, 4, 5, 6, Part A, Part B, including change from MCC to SAHPRA	Version 2, June 2018