SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

SAFETY REPORTING DURING CLINICAL TRIALS FORM

This is intended for all Investigators/Sponsor/Applicants conducting clinical trial in South Africa. This has been prepared to serve as a form to those reporting serious adverse events occurring during the use of registered or unregistered medicines in approved clinical trials.

Instructions:

1. Complete all parts of this form, sign and date the form.
2. This form should be used for reporting of both initial and follow-up safety reports.
3. This form should preferabbly be typed.

PART 1: ADMINISTRATIVE DETAILS	
1.1 Study Title or abbreviated title	
1.2 Protocol Number	
1.3 SAHPRA reference number	

PART 2: SITE INFORMATION	
2.1 Name and address of site	
2.2 Name of Principal Investigator	

PART 3: PARTICIPANT INFORMATION	
3.1 Participant trial ID	
3.2 Age	
3.3 Gender	
3.4 Relevant pre-medical history summary	

PART 4: SAE INFORMATION (where possible, tick (√) the appropriate box)	
4.1 Type of report	☐ Initial ☐ Follow-up ☐ Final
4.2 Reaction onset date	YYYY/MM/DD
4.3 Reaction stop date	YYYY/MM/DD
4.4 Outcome of adverse event	☐ Participant died ☐ Hospitalisation or prolongation ☐ Life threatening ☐ Congenital abnormality/ Birth defects ☐ Persistent or significant disability/incapacity ☐ Other (list)_____
4.5 Description of event summary	
4.6 Relationship of event to study product (causality)	☐ Definitely ☐ Probably related ☐ Possibly related ☐ Unrelated
4.7 Was study product discontinued due to event ?	☐ Yes ☐ No ☐ N/A

4.8 Describe steps taken to manage SAE (narrative)	
4.9 Did adverse event abate after withdrawal of study product?	☐ Yes ☐ No ☐ N/A
4.10 Did adverse event reappear after re-initiation of product?	☐ Yes ☐ No ☐ N/A
4.11 Crucial additional information	

PART 5: SUSPECTED MEDICINE (S) INFORMATION	
5.1a List suspected product(s) including Investigational Product (IP)	
5.1b List suspected concomitant or comparator medicine(s)	
5.2 Route(s) of administration	☐ Intravenous injection/Intravenous infusion (IV/IVI) ☐ Intramuscular ☐ Sub-cutaneous ☐ Topical ☐ Oral ☐ Sub-lingual ☐ Rectal ☐ Vaginal ☐ Other (list)_____
5.3 Dose(s)	
5.4a Indication(s) for use of IP	
5.4b Indication for concomitant medicines	
5.5a Date of initiation of treatment of IP	YYYYY/MM/DD
5.5b Date of initiation of treatment of comparator or concomitant	YYYYY/MM/DD
5.6 Therapy duration (prior to onset of SAE)	

PART 6: FINAL OUTCOME	
6.1 What was the final outcome of the SAE?	☐ Ongoing ☐ Recovered completely ☐ Recovered with sequelae ☐ Permanent ☐ Died
	Date related to above:

PART 7: CONTACT DETAILS	
7.1 Name of applicant	
7.2 Contact details	
7.3 Signature and date	

PART 8: PERSON COMPLETING THE FORM	
8.1 Name and designation of person completing this form	
8.2 Signature and date	

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UPDATE HISTORY

Date	Reason for Update	Version & Publication
September 2017	Approved for Implementation	v1 October 2017
July 2019	Published for implementation	v1 August 2019
November 2019	Reporting timelines, removed on form	V2 November 2019