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 preferably 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)

<table>
<thead>
<tr>
<th>4.1 Type of report</th>
<th>Initial</th>
<th>Follow-up</th>
<th>Final</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.2 Reaction onset date</td>
<td>YYYY/MM/DD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.3 Reaction stop date</td>
<td>YYYY/MM/DD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.4 Outcome of adverse event</td>
<td>Participant died</td>
<td>Hospitalisation or prolongation</td>
<td>Life threatening</td>
</tr>
<tr>
<td>4.5 Description of event summary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.6 Relationship of event to study product (causality)</td>
<td>Definitely</td>
<td>Probably related</td>
<td>Possibly related</td>
</tr>
<tr>
<td>4.7 Was study product discontinued due to event?</td>
<td>Yes</td>
<td>No</td>
<td>N/A</td>
</tr>
</tbody>
</table>
### 4.8 Describe steps taken to manage SAE (narrative)

<p>| | |</p>
<table>
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</table>

### 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

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### PART 5: SUSPECTED MEDICINE (S) INFORMATION

#### 5.1a List suspected product(s) including Investigational Product (IP)

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#### 5.1b List suspected concomitant or comparator medicine(s)

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</table>

#### 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)

<p>| | |</p>
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#### 5.4a Indication(s) for use of IP

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#### 5.4b Indication for concomitant medicines

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</table>

#### 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)

<p>| | |</p>
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</table>
## 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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E-mail to SAHPRA within 7 days of knowledge of the SAE
E-mail to: ctcsaes@sahpra.org.za

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### UPDATE HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason for Update</th>
<th>Version &amp; Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2017</td>
<td>Approved for Implementation</td>
<td>v1 October 2017</td>
</tr>
<tr>
<td>July 2019</td>
<td>Published for implementation</td>
<td>v1 August 2019</td>
</tr>
</tbody>
</table>