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 be typed.

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

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

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

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| **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 |  |

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| **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) |  |

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| **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 |  |

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| **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**

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| **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 |
| April 2020 | Administrative Changes | V3 April 2020 |
| October 2022 | Final form for implementation (Alignment with SAHPRA template and new document number) | V4 October 2022 |