**SAE REPORTING SOP, OCTOBER 2023, V1**

Research Ethics Committee

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| **Final Version** | **Reason for Amendment** | **Effective Date** |
| 1 | Developed and published for implementation | October 2023 |
|  | Administrative changes | March 2024 |

Please note SAMAREC Accepts SAHPRA Reports, (SAHPRA, 2023)

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| **PART 1: ADMINISTRATIVE DETAILS** | |
| 1.1 Protocol Title |  |
| 1.2 Protocol Number |  |
| 1.3 SAMAREC 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: |

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| **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 |  |

Please email through to [samarec@samedical.org](mailto:samarec@samedical.org)

# Acknowledgements

SAHPRA. (2023, October 06). *SAHPRA.* Retrieved from SAHPRA: http://www.sahpra.org.za