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| **Project Title:** |  |
| **Form to be emailed to:** |  |

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| Participant Demographics | | |
| Participant Initials: \_\_\_ /\_\_\_ / \_\_\_ | Year of birth: | |
| Participant Trial ID: | Gender at birth:  Male | Female |

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| AE/SAE Report Details | | | | | | |
| Event Title: | | | | | | |
| Previous event Title (if applicable): | | | | | | |
| Onset Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ | | Resolution Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_  Ongoing | | | Report Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ | |
| Event type:  AE  SAE  AESI | | Initial Report | | | Follow Up Report # \_\_ \_\_ | |
| Grade:  Mild (Grade 1) | Moderate (Grade 2) | | Severe (Grade 3) | Life threatening (Grade 4) | | Fatal (Grade 5) |

*AE = Adverse Event SAE = Serious Adverse Event AESI = Adverse Event of Special Interest*

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| Event Category | | |
| Life threatening | Persistent/significant disability or incapacity | Congenital abnormality/birth defect |
| Death | Important medical event | Non-Serious [AESI] |
| Hospitalisation required | Admission Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ | Discharge Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_  *\*provide discharge summary* |
| Prolonged hospitalisation | Admission Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ | Discharge Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_  *\*provide discharge summary* |
| Event Outcome | | |
| Not recovered/Un-resolved | | |
| Recovered/Resolved | Date of Resolution (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ | |
| Recovering/Resolving |
| Recovered/Resolved with sequelae |
| Death | Date of Death (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_  *\*provide death certificate* | Autopsy performed?  Yes  No  *\*provide autopsy report* |
| Unknown |  |  |

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| Event Narrative |
| Briefly describe the sequence of event onset, diagnosis and outcome. Include rationale for causality and any interventions given. Please describe actions taken with study drug (s). Please attach a discharge summary or note if one is not available.  Please make sure that all confidential information is redacted prior to attaching any documents |
| Site awareness Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ |
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| Study treatment/procedure/intervention detail | | | | | | | |
| Start Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_  Not applicable (pre administration event) | | | | Stop Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ | | | |
| Batch/Lot #:  Not applicable | Dose: | | Unit: | | Route: | | Frequency: |
| Relation to study treatment/procedure/intervention | | | | | | | |
| Not applicable | | Related (please specify) | | | | Not related | |
| Action Taken with study drug due to Event | | | | | | | |
| Not Applicable | Dose not changed | | Drug Interrupted | | Drug withdrawn | | Unknown |

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| Laboratory/Diagnostic Tests  Yes  No | | | | |
| Test Name | Date  (dd/mmm/yyyy) | Result | Unit | Normal Range |
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| Concomitant Medications  Yes  No  (additional entries may be included in the narrative section if needed) | | | | | | | |
| Drug  (Pharmaceutical Name) | Indication | Dose/Units | Freq. | Route | Start Date  (DD-MMM-YYYY) | Ongoing | Stop Date  (DD-MMM-YYYY) |
|  |  |  |  |  |  | Yes  No |  |
|  |  |  |  |  |  | Yes  No |  |
|  |  |  |  |  |  | Yes  No |  |
|  |  |  |  |  |  | Yes  No |  |

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| Any other relevant Information  Yes  No |
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| Reporter Information | | |
| Investigator Name: | Signature: | Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ |
| Reporter Name (if not investigator): | Signature: | Date (dd/mmm/yyyy): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ |