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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): \_\_ \_\_/ \_\_ \_\_ \_\_/ \_\_ \_\_ \_\_ \_\_ |