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| **Protocol Number** |  | **MCA CT Number** |  |
| **PACTR No** |  | **Other numbers** |  |
| **Principal Investigator** |  |
| **Clinical Trial Site** |  |

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| **Subject Information (at time of SAE onset)** |
| **Subject ID** |  | **Date of Birth** | **\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_****Day / Month / Year** | **Age** | **Sex** |

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| **Serious Adverse EVENT** |
| **Event onset** | **\_\_\_\_\_/\_\_\_\_\_\_/\_\_\_\_\_\_****Day / Month / Year** | **Outcome of Event****[ ]  Ongoing [ ]  Recovered [ ]  Unknown** |
| **Tick all appropriate to adverse event**[ ]  **Subject died** [ ]  **Involved or prolonged hospitalisation**[ ]  **Life thretening** [ ]  **Involved persistence or significant disability or incapacity** |
| **Describe event(s) in detail (including relevant tests/lab data)** |

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| **Investigational Medicinal Product Information** | **Blinded:** [ ]  Yes [ ]  No |
| **IMP Name/Identifier** | **Route** | **Daily Dose/Unit** | **Start date****Day/Month/Year** | **Stop date****Day/Month/Year** |
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| **Concomitant medication or Auxiliary Medicine (exclude those used to treat event)** |
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| **Generic name** | **Indication** | **Daily Dose** | **Route** | **Start date****Day/Month/Year** | **Stop date****Day/Month/Year** |
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| **Assessment of causality with IMP**  |
| **SAE is related to IMP:**  | Definite [ ]  | Probable [ ] Possible [ ]  | Unlikely [ ] Unrelated [ ]  |
| **Did event abate after stopping IMP** | [ ]  Yes [ ]  No [ ]  NA | **Did event reappear after IMP reintroduction** | [ ]  Yes [ ]  No [ ]  NA |

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| **TYPE OF REPORT** |
| **Date of this report** | \_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_\_**Day / Month / Year** | **Date site aware of SAE** | \_\_\_ / \_\_\_\_\_ / \_\_\_\_\_\_**Day / Month / Year** |
| [ ]  **Initial Report**  [ ]  **Follow-up** **report # \_\_\_\_\_** |

**Principal Investigator Signature Date**

**OFFICIAL USE**

|  |  |
| --- | --- |
| **Date received**:  | **MCA SAE number**:  |
| **Comments:**   |