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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** |

|  |  |  |
| --- | --- | --- |
| **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)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **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:** | |