**MEDICINES CONTROL AGENCY**

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia  
Website: [www.mca.gm](http://www.mca.gm); E-mail: [info@mca.gm](mailto:info@mca.gm); Tel. No.: +2204380632

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

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| **Participant Information (at time of SAE onset)** | | | | | |
| **Participant 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**  **Participant died**  **Involved or prolonged hospitalisation**  **Life threatening**  **Involved in persistent orsignificant 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:** | |