**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; 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) |
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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**  |
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| **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**

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