**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220)4380632, [www.mca.gm](http://www.mca.gm)

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| SECTION A ADMINISTRATIVE INFORMATION | | | |
| Frequency of Report: Annually  Every 6 months  Quarterly  Other (*specify*) | | | |
| **Title of Clinical Trial:** | | | |
| **Principal Investigator:** (*name, address, email, phone*) | | | |
| **Other Study Contact (if applicable):** (*name, address, email, phone*) | | | |
| Protocol Number: | | MCA CT Number: | |
| PACTR Number: | | Other: | |
| Planned Start Date: | | Actual Start Date: | |
| Reporting period (From–To): |  | |  |
| **Date of this report:** | | | |

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| SECTION B Trial Status (Tick only one category) |
| Enrolment has not begun  Actively enrolling participants  Participants are receiving treatment/intervention  Participants are in follow-up only  Laboratory tests ongoing  Analysing data  Data analysis completed |

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| SECTION C Information on Participants | |
| Number of participants consented and screened |  |
| Total number of participants consented and screened who are eligible for the trial |  |
| Number of participants to which the investigational product(s) has been administered |  |
| Number of participants left to be enrolled until end of trial |  |
| Number of participants who have discontinued the study | |
| by Investigator |  |
| voluntarily |  |
| due to SAE |  |

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| SECTION D Information on Trial Activities | | | | |
| Have there been any Serious Adverse Events (SAEs) | Yes |  | No |  |
| Total number of AEs relevant with respect to nature or frequency since start of the trial  (attach line list of relevant AEs) |  | | | |
| Total number of SAEs since start of the trial  (attach line list of all SAEs) |  | | | |
| Total number of SARs suspected to be related to the IP(s) and fatal SAEs since start of the trial |  | | | |
| Have these been reported to MCA | Yes |  | No |  |
| If No, explain: | | | | |
| Have there been any changes to the clinical trial since authorisation by MCA | Yes |  | No |  |
| If Yes, have they been submitted to MCA | Yes |  | No |  |
| If No, explain: | | | | |
| Planned date for the end of the trial |  | | | |

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| SECTION E Comments (if any) |
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**List the documents attached to this report**

I, the undersigned certify that the information submitted in this report is accurate.

Signature of Principal Investigator in The Gambia:

Signature Date