**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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| SECTION A ADMINISTRATIVE INFORMATION |
| Frequency of Report: [ ]  Annually [ ]  Every 6 months [ ]  Quarterly [ ]  Other (*specify*):  |
| **Full Title of Clinical Trial:**  |
| **Details of Principal Investigator:** |
| Name |  |
| Address |  |
| Email |  |
| Telephone |  |
| **Other Study Contact (if applicable):** |
| Name |  |
| Address |  |
| Email |  |
| Telephone |  |
| Sponsor: |  |
| Protocol Number:  | MCA CT Number:  |
| PACTR Number:  | Other:  |
| Planned Start Date:  | Actual Start Date:  |
| Date of favourable opinion of Ethics Committee:  |  |
| Reporting period (From–To):  |  |  |
| **Date of this report:**  |

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| SECTION B COMMENCEMENT AND TERMINATION DATES |

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| **Has the study started in The Gambia?** | [ ]  **Yes** [ ]  **No** |
| **If yes, what was the actual start date in The Gambia?** |  |
| **If no, what are the reasons for the study not commencing in The Gambia?** |  |
| **What is the expected start date?***Please note, if the study will not start within 24 months of the ethics Favourable Opinion date the Ethics Committee may review its’ opinion.* |  |
| **Has the study finished?***If yes, complete and submit the end of trial notification form.* | [ ]  **Yes** [ ]  **No** |
| **If no, what is the expected completion date?** |  |
| **If you expect the study to overrun the planned completion date, what are the reasons for this?** |  |
| **If you do not expect the study to be completed, give reason(s):** |  |

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| SECTION C SITE INFORMATION |
| Number of The Gambia trial sites proposed in original application: |  |
| Number of The Gambia trial sites recruited to date: |  |

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| **Do you plan to increase the total number of The Gambia trial sites proposed for the study?***Please note, the addition of any new trial sites not listed in the original application should be submitted as an amendment.* | [ ]  **Yes** [ ]  **No** |

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| SECTION D Information on Participants  |
| Number of participants consented and screened: |  |
| Total number of participants consented and screened who are eligible for the study: |  |
| Number of participants to which the investigational product(s) has been administered: |  |
| Number of participants left to be enrolled until end of study: |  |
| Number of participants who have discontinued the study |
|  by Investigator: |  |
|  Voluntarily: |  |
|  due to SAE: |  |
| Total study withdrawals: |  |
| Number of treatment failures to date (prior to reaching primary outcome) due to |  |
|  (a) adverse events: |  |
|  (b) lack of efficacy: |  |
| Total number of treatment failures: |  |

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| SECTION E Information on Trial Safety and 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 study:*(attach line list (MCA-F-501/14) of relevant AEs)* |  |
| Total number of SAEs since start of the study:*(attach line list (MCA-F-501/14) of all SAEs)* |  |
| Total number of SARs suspected to be related to the IMP(s) and fatal SAEs since start of the study: |  |
| Have these been reported to MCA? | [ ]  Yes [ ]  No |
| If No, explain:  |
| Have there been any changes to the study 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 study: |  |

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| SECTION F AMENDMENTS  |
| Have any substantial amendments been made to the study during the reporting period? | [ ]  Yes [ ]  No |
| If yes, give the date and amendment number for each substantial amendment made: |  |

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| SECTION G SERIOUS deviations from the PROTOCOL OR GOOD CLINICAL PRACTICE (GCP) |
| Have any serious deviations from the protocol or GCP occurred in the study during the reporting period? | [ ]  Yes [ ]  No |
| If yes, describe the deviation: |  |

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| SECTION G 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