**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

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

|  |
| --- |
| SECTION B COMMENCEMENT AND TERMINATION DATES |

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

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

|  |  |
| --- | --- |
| **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** |

|  |  |
| --- | --- |
| 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: |  |

|  |  |
| --- | --- |
| 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: |  |

|  |  |
| --- | --- |
| 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: |  |

|  |  |
| --- | --- |
| 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: |  |

|  |
| --- |
| SECTION G Comments (if any) |
|  |

**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