	CLINICAL TRIAL PROGRESS REPORT	MCA-F-501/07

MEDICINES CONTROL AGENCY

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia
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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:			

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:

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Signature Date