



CLINICAL TRIAL PROGRESS REPORT

MCA-F-501/07

MEDICINES CONTROL AGENCY

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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:

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

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	

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			

SECTION E	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