



# CLINICAL TRIAL/STUDY SUMMARY REPORT

MCA-F-501/10

## MEDICINES CONTROL AGENCY

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### SECTION A ADMINISTRATIVE INFORMATION

**Title of Clinical Trial/Study:**

**Sponsor:** *(Please insert name and address),*

**Principal Investigator:** *(Please insert name, address, email, phone)*

**Protocol Number**

**MCA CT Number**

**PACTR Number**

**Other numbers**

**Date of Start of the Trial/Study:**

**Date of End of the Trial/Study:**

**Date of interim data analysis,  
if any:**

**Date of final data analysis:**

**Was it an early termination**

☐ Yes

☐ No

**Date of this report:**

### SECTION B General Information about the Clinical Trial/Study

**Main objectives of the trial/study:**

**Trial/study design:**

**Scientific background and explanation of rationale:**

**Measures of protection of participants taken:**

**Background therapy:**

**Statistical methods used:**

#### **SECTION C POPULATION OF PARTICIPANTS IN THE GAMBIA**

**Inclusion criteria**

**Exclusion criteria**

**Number of participants screened**

**Number of participants recruited**

**Number of participants included in the clinical trial/study**

**Number of participants withdrawn**

#### **SECTION D INVESTIGATIONAL PRODUCTS**

**Description of investigational products used:**

**Randomisation details:**

**Blinding details** (if applicable):

**Accountability** (repeat information for each product):

**Total quantity imported**  
**Total quantity purchased locally**  
**Total quantity used in the trial**  
**Total quantity wasted (spilled/lost)**  
**Total quantity onsite** (if applicable)  
**Total quantity returned to sponsor** (if applicable)  
**Total quantity disposed** (if applicable)

## SECTION E BASELINE CHARACTERISTICS

**Age and age group breakdown**

**Gender and gender breakdown**

**Trial/Study Specific Characteristic**  
(if applicable)

## SECTION F END POINTS

**End point definitions\*:**

**End Point #1 Statistical Analyses:**

**End Point #2 Statistical Analyses:**

\*Information shall be provided for as many end points as defined in the protocol

## SECTION G ADVERSE EVENTS

**Description of overall adverse event experience:**

**Summary and narratives of serious adverse events, indicating those suspected**

**SECTION G ADVERSE EVENTS****to be related to the IMP** (attach tables)**Summary of non-serious adverse events** (attach tables)**SECTION H ADDITIONAL INFORMATION****Substantial Modifications:****Interruptions and re-starts****Limitations:****Sources of potential bias and imprecisions:*****For clinical trials/studies replicating trials/studies on already authorised investigational products and used in accordance with the terms of the marketing authorisation*****Indicate identified concerns to relevant aspects of the efficacy of the IP****SECTION I OVERALL RESULTS OF THE CLINICAL TRIAL/STUDY*****List the documents attached to this report***

I, the undersigned certify that this clinical trial was conducted in compliance with ICH-GCP Guideline including the archiving of essential documents, and any applicable regulatory requirements, and that the information submitted in this report is accurate and complete.

Signature of Principal Investigator in The Gambia:

.....  
Signature.....  
Date