**MEDICINES CONTROL AGENCY**

Kairaba Avenue, K.S.M.D. Pipeline, The Gambia. Telephone: (+220)4380632, [www.mca.gm](http://www.mca.gm)

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| SECTION A ADMINISTRATIVE INFORMATION | | | | | | | |
| **Title of Clinical Trial:** | | | | | | | |
| **Sponsor:** (*Please insert name and address),* | | | | | | | |
| **Principal Investigator:** (*Please insert name, address, email, phone*) | | | | | | | |
| Protocol Number |  | MCA CT Number |  | | | | |
| PACTR Number |  | Other |  | | | | |
| Date of Start of the Trial: | |  | | | | | |
| Date of End of the Trial: | |  | | | | | |
| Date of interim data analysis, if any: | |  | | | | | |
| Date of final data analysis: | |  | | | | | |
| Was it an early termination | | | | Yes |  | No |  |
| **Date of this report:** | | | | | | | |

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| SECTION B General Information about the Clinical Trial |
| **Main objectives of the trial:** |
| Trial design: |
| Scientific background and explanation of rationale: |
| Measures of protection of subjects taken: |
| Background therapy: |
| Statistical methods used: |

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| SECTION C Population of subjects in The Gambia | |
| **Inclusion criteria** |  |
| **Exclusion criteria** |  |
| **Number of subjects screened** |  |
| Number of subjects recruited |  |
| **Number of subjects included in the clinical trial** |  |
| Number of subjects withdrawn |  |

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| 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  Total quantity disposed |  |

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| SECTION E Baseline Characteristics | |
| Age and age group breakdown |  |
| Gender and gender breakdown |  |
| Study Specific Characteristic  (if applicable) |  |

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| 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 |
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| Description of overall adverse event experience: |
| Summary and narratives of serious adverse events, indicating those suspected to be related to the IP (attach tables) |
| Summary of non-serious adverse events (attach tables) |

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| SECTION H Additional Information | |
| Substantial Modifications: | |
| Interruptions and re-starts |  |
| Limitations: | |
| Sources of potential bias and imprecisions: | |
| *For clinical trials replicating 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 | |

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| SECTION I overall results of the clinical trial |
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**List the documents attached to this report**

I, the undersigned certify that this clinical trial was conducted in compliance with ICH E6-GCP Guideline including the archiving of essential documents, and any applicable regulatory requirements, and that the information submitted in this report is accurate.

Signature of Principal Investigator in The Gambia:

Signature Date