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|---|---|---|
| | **NON-INTERVENTIONAL STUDY REPORT** | MCA-F-501/13 |

**MEDICINES CONTROL AGENCY**

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

| **SECTION A ADMINISTRATIVE INFORMATION** | | | | | |
|---|---|---|---|---|---|
| **Study Title:** | | | | | |
| **Responsible Person:** (*Please insert name and address),* | | | | | |
| **Study identification, where applicable** | | | | | |
| **Date of Start of the Study:** | | | | | |
| **Date of End of the Study:** | | | | | |
| **Was it an early termination** | | Yes | | No | |
| **Date of this report:** | | | | | |

| **SECTION B General Information about the Clinical Trial** |
|---|
| **Purpose/ Rationale of the study:** |
| **Substantial Modifications:** |
| **Statistical methods used:** |
| **Objectives of Study:** |

| | |
|---|---|
| **Number of patients observed in the study:** | |

| **SECTION D PRODUCTS AND ADVERSE EVENTS** |
|---|
| **Description of products used:** |
| **Description of overall safety experience:** |
| **Summary and narratives of serious adverse reactions suspected to be related to the product** (attach tables) |

| **SECTION E OVERALL RESULTS OF THE CLINICAL TRIAL** |
|---|
| |

***List the documents attached to this report***

Signature of Responsible Person:

..... .....

Signature Date