**MEDICINES CONTROL AGENCY**

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia  
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|  |  |
| --- | --- |
| A Trial Identification | |
| PACTR Number: |  |
| Protocol Number: |  |
| Full Title of Clinical Trial: | |

|  |
| --- |
| B APPLICANT IDENTIFICATION *(please tick the appropriate box)* |

|  |  |
| --- | --- |
| Sponsor |  |
| Legal representative of the sponsor |  |
| Person or organisation authorised by the sponsor to make the application |  |
| **Complete below:** |  |

|  |  |
| --- | --- |
| Organisation |  |
| Name of person to contact |  |
| Address |  |
| Telephone number |  |
| Email |  |

|  |  |
| --- | --- |
| C End of trial | |
| Is this the end of the trial in The Gambia only1 | Yes  No |
| If yes, give date (DD/MM/YYYY): |  |

|  |  |
| --- | --- |
| **Is this the end of the complete trial in all countries concerned by the trial1** | Yes No |
| If yes, give date (DD/MM/YYYY): |  |
| **Is it an early termination?** | Yes No |
| If yes, give date (DD/MM/YYYY): |  |
| **Briefly describe in an annex (free text):** | |
| * The justification for early termination of the trial | |
| * Number of participant still receiving treatment at time of early termination in The Gambia and their proposed management; | |
| * The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product | |

**1** In case of a multi-country trial, if the national and global end of trial dates are different submit this form two times:

1) At the end of the trial in The Gambia

2) At the global end of the trial

**Declaration by the Applicant**

I hereby confirm that/confirm on behalf of the sponsor that (*delete which is not applicable*):

* The above information given on this declaration is correct; and
* That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the MCA Guideline for Clinical Trials in Humans

Name:

Signature Date

|  |  |
| --- | --- |
| For official use |  |
| Date of receipt |  |
| MCA registration number |  |
| Ethics committee registration number |  |