



NOTIFICATION OF THE END OF A CLINICAL TRIAL

MCA-F-501/15

MEDICINES CONTROL AGENCY

Off Bertil Harding Highway, Kotu East, Kanifing Municipality, P.O. Box 3162, Serekunda, The Gambia
Website: www.mca.gm; E-mail: info@mca.gm; Tel. No.: +2204380632

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

<ul style="list-style-type: none"> • Number of participant still receiving treatment at time of early termination in The Gambia and their proposed management;
<ul style="list-style-type: none"> • 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	