

	OBSERVATIONAL PHASE IV CLINICAL STUDY APPLICATION FORM	MCA-F-501/12
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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

*Write NA if an item is not applicable

Section 1: Study identification	
Study title	
Observation Plan, date, and version ¹	
Study identification, where applicable	
Purpose of the study	<input type="checkbox"/> PASS <input type="checkbox"/> PAES <input type="checkbox"/> Other If other, specify:
Status	<input type="checkbox"/> Commercial <input type="checkbox"/> Non-commercial

¹ Any translation of the observation plan should be assigned the same date and version as those in the original document

Section 2: Identification of the Responsible Persons	
Name of the responsible person	
Qualification	
MDCG Registration number, if applicable	
Address	
Telephone number	
E-mail	
Website (if applicable)	
<i>Persons the responsible person has delegated functions to²</i>	
Name of the organisation	
Address	
Name of the person	
Function	
Telephone number	
E-mail	

² Repeat as necessary

Section 3: Details of location³	
Name of location	
Physical address	
Contact person including telephone and email	
Website (if applicable)	

³ Repeat as necessary

Section 4: Information on the Products under observation⁴	
Name of the product	
Marketing Authorisation Holder	
Manufacturer	
Marketing Authorisation Number	
ATC code(s) of medicine	
Pharmaceutical form of medicine	
Strength	
Dosage Regimen	
Route of administration/application	
Name of each active substance of medicine (INN)	
Is the medicine (if applicable)? <ul style="list-style-type: none"> • Immunological product (vaccine, allergen, immune serum) • Plasma derived product • Recombinant product • Radiopharmaceutical product • Herbal medicinal product • Other, specify 	
Is the related product (if applicable)? <ul style="list-style-type: none"> • Medical device • Cosmetic • Homeopathic medicine Other, specify	
Date of publication of the product information	

⁴ Present this information for each product to be under observation

Section 5: Information on the patients⁵

Medical condition or disease ⁵ the product is prescribed for	
Number of patients	

⁵ Present this information for each product to be under observation

Section 6: Study duration

Total duration of the study	
Start date	
End date	

DECLARATION BY THE APPLICANT

I, the undersigned have submitted all requested and required documentation, and have disclosed all information that may influence the approval of this application.

I, hereby declare that all information contained therein, or referenced by, this application is complete and accurate and is not false or misleading.

Signature of the Responsible Person

 Name Signature Date

OFFICIAL USE

Date received:	MCA-number:
Comments	
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