



NON-INTERVENTIONAL STUDY APPLICATION FORM

MCA-F-501/12

MEDICINES CONTROL AGENCY

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

*Write N/A 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	

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 Person	
Name of the responsible person	
Name of the organisation, if applicable	
Address	
Telephone number	
E-mail	
Website (if applicable)	
Qualification (Medical doctor, other)	
Status	Commercial <input type="checkbox"/> Non-commercial <input type="checkbox"/>
<i>Persons the responsible person has delegated functions to²</i>	
Name of the organisation	
Name of the person	
Function	
Professional Address	
Telephone number	
E-mail	
Website (if applicable)	

2 Repeat as necessary

Section 3: Details of location³	
Name of location	
Physical address	
Contact person including telephone and email	
Name(s) of the medical doctor (s)	
MDCG Registration number(s)	

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

