	CLINICAL TRIAL APPLICATION FORM	MCA-F-501/01

MEDICINES CONTROL AGENCY

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*Write N/A if an item is not applicable

Section 1: Trial identification	
Other countries to which the application is submitted	
PACTR[1] number	
Trial title	
Trial short title where available	
Protocol number, date, and version[2]	
Phase of the trial (if applicable)	
If applicable: additional international trial identifiers: WHO, clintrials.gov, EudraCT, etc	

1 Pan African Clinical Trials Registry

2 Any translation of the protocol should be assigned the same date and version as those in the original document

Section 2: Regulatory details	
Name of other Regulatory Authorities and Ethics Committees to which this application has been submitted, and/or approved	
If applicable, explain why the trial is not going to be conducted in the host country of the sponsor	
If applicable, name of other Regulatory Authorities and/or Ethics Committees that have rejected this trial and explain	
If applicable, provide details and explain why this trial was halted at any stage by other Regulatory Authorities and/or Ethics Committees	

Section 3: Identification of the Sponsor(s)	
Sponsor	
Name of the organisation	
Name of the contact person(s)	
Address	
Telephone number	
E-mail	
Website (if applicable)	
Funding body(s) *(if different from Sponsor)*	
Name of the organisation	
Name of the contact person(s)	
Address	
Telephone number	
E-mail	
Website (if applicable)	
Sponsor's representative	
Name of the organisation	
Name of the contact person	
Address	
Telephone number	
E-mail	
Status	Commercial ☐ Non-commercial ☐
Website (if applicable)	
Monitor	
Name of the organisation (if other than Sponsor or Sponsor's representative)	
Name of the contact person	
Address	
Telephone number	
E-mail	

Section 4: Applicant identification	
State who is submitting the application: Sponsor, Sponsor's representative or Principal Investigator	
Name of the organisation	
Name of the contact person	
Address	
Telephone number	
E-mail	

Section 5: Investigators' details	
Coordinating Investigator for multicentre trials *(if applicable)*	
Name	
Qualification (Medical doctor, other)	
Professional address	
Telephone number	
E-mail	
Principal Investigator in The Gambia	
Name	
Qualification (Medical doctor, other)	
MDCG Registration number (if responsible medical doctor):	
Professional address	
Telephone number	
E-mail	
Clinical Trial coordinator *(where appointed by Principal Investigator)*	
Name	
Qualification (Medical doctor, other)	
Professional address	
Telephone number	
E-mail	
Principal Investigator(s) of other sites *(if applicable) - repeat as necessary*	
Name	

Qualification (Medical doctor, other)	
Professional address	
Telephone number	
E-mail	
Responsible Medical Doctor *(if different from PI)*	
Name	
MDCG Registration number:	
Professional address	
Telephone number	
E-mail	
Investigator(s) *listed in the protocol (if applicable) - repeat as necessary*	
Name	
Qualification (Medical doctor, other)	
Professional address	
Telephone number	
Fax number	
E-mail	

Section 6: Details of Trialists and Sites	
Details of the site(s): name, physical address, contact details, contact person including telephone and email contacts	
Details on the staff (Clinical Trial team) at the site (number, qualification and roles)	
Evidence of the Lab(s) competences:[3] Name and address of responsible Lab Manager	

3 Repeat as necessary

Section 7: Information on the Investigational Medicinal Product/s (IMP)/Investigational Product/s (IP)[4]	
Indicate if the information refers to the IMP/IP being tested or to the IMP/IP used as a comparator[5] - repeat as necessary	
Status of the IMP/IP	

Is the IMP/IP prequalified[6] by WHO?	
Does the IMP/IP have a registration in any country?	
If yes, provide the trade name, name of the marketing authorisation holder and the country that granted registration.	
Is registration[7] in Africa envisioned?	
For the purpose of this trial, is the IMP/IP modified in relation to its registration?	
IMPD or equivalent submitted: • IMPD • Summary of Product Characteristics (SmPC) or other Professional Product Information	
Has this IMP/IP been previously authorised in a clinical trial conducted by the Sponsor in Africa? If so, provide the Authority's name, date, approval number (if available), trial title, protocol number, [national] Principal Investigator, and date of the final report (if available)	
Description of the IMP/IP	
Product name or identification number	
ATC code of IMP if officially registered	
Pharmaceutical form of IMP	
Pediatric formulation of IMP? Y/N	
Maximum duration of treatment of a patient/participant according to the protocol	
Dose of IMP allowed: • First dose for first-in-human trials, specify per day or total dose; units and route of administration • Maximum dose allowed, specify per day or total dose; units and route of administration	
Estimated quantity of IMP/IP required for the trial (including overage[8])	
Route of administration/application	

Name of each active substance of IMP (INN or proposed INN, if available)	
Strength of IMP (specify all strengths to be used): • Concentration unit • Concentration type (exact number, range, more than, or up to) • Concentration (number) • Unit of issue	
Type of IMP/IP	
Does the IMP contain an active substance of chemical or of biological/ biotechnological origin?	
Is the IMP? • Immunological product (vaccine, allergen, immune serum) • Plasma derived product • Recombinant product • Radiopharmaceutical product • Herbal medicinal product • Other, specify	
Is the IP? • Medical device • Cosmetic • Homeopathic medicine Other, specify	

4 Present this information for each and all investigational (medical) products to be used in the trial

5 Include a justification for choosing this comparator

6 Provide the corresponding evidence

7 If more than one IMP/IP is being tested, indicate for which IMP/IP registration is envisioned, if applicable

8 Provide a justification if the overage is higher than 20%

Section 8: Medical condition or disease under investigation	
Medical condition/disease to be investigated; summarise the local epidemiology (up to 100 words)	
Therapeutic area	

Section 9: Scope of the trial	
Diagnosis	

Prophylaxis	
Therapy	
Safety	
Efficacy	
Other, explain	

Section 10: Trial type	
Human pharmacology (Phase I) Human pharmacokinetics First-in-humans Bioequivalence Other, specify	
Therapeutic exploratory (Phase II)	
Therapeutic confirmatory (Phase III)	
Therapeutic use (Phase IV)	
Other, specify	

Section 11: Trial duration and recruitment	
Total duration of the study including follow-up	
Envisioned number of participants globally	
Envisioned number of participants nationally	
Envisioned number of participants per site in the country to which the application is being submitted	

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.

Ie, the undersigned will ensure that if the above-said clinical trial is approved, it will be conducted according to the protocol submitted, and all applicable legal, good clinical practice, ethical and regulatory requirements.

Signature of Applicant

Name	Signature	Date
.....	.....	.....

OFFICIAL USE

Protocol number:	Application fee: .....
Comments	
MCA CT Number:	