**MEDICINES CONTROL AGENCY**

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\*Write N/A if an item is not applicable

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| **Section 1: Trial identification** | |
| Other countries to which the application is submitted |  |
| PACTR1 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

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| **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 |  |

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| **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 |  |

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| **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 |  |

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| **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 |  |

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| **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

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| **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%

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

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| **Section 9: Scope of the trial** | |
| Diagnosis |  |
| Prophylaxis |  |
| Therapy |  |
| Safety |  |
| Efficacy |  |
| Other, explain |  |

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| **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 |  |

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| **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**

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