African Vaccine Regulatory Forum (AVAREF)

Clinical Trial Application Form

Trial's full title	
Short title	
Protocol No.	
Version No.	
Investigational product	
Sponsor:	
Contact person:	
Address:	
Telephone No.:	
Fax No.:	
Cell No.:	
E-mail address:	
Date of application	

Request for authorisation from the National Regulatory Authority

Part 1: Trial identification	
1.X Countries to which the application is submitted ➔relevant for multinational trials	
1.X PACTR number	
1.1 Trial's title	
1.1.1 Trial's short title where available	
1.2 Protocol No, date and version[1]	
1.3 Phase of the trial	
1.X Additional international trial identifiers: WHO, clintrials.gov, etc	
1.X Is this a resubmission?[2]	
Part X: Regulatory details	
xx Name other Regulatory Authorities or Ethics Committees to which this application has been submitted, and/or approved	
xx If applicable, explain why the trial is not going to be conducted in [ ] the host country of the applicant/sponsor	
xx If applicable, name other Regulatory Authorities or Ethics Committees that have rejected this trial and explain	
xx If applicable, provide details and explain why this trial was halted at any stage by other Regulatory Authorities	
Part X: Identification of the sponsor responsible for the application	
Sponsor	
X.x Name of the organisation	
X.x Name of the contact person	
X.x Address	
X.x Telephone number	
X.x Fax number	
X.x E-mail	
Sponsor's legal representative in the countries where approval is sought	
x.x Name of the organisation	

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

[2] For a resubmission following previous withdrawal of an application or unfavourable opinion of an ethics committee, or previous withdrawal of an application or refusal of a request by the competent authority, enter a letter in the sequence, A for first resubmission, B for second, C for third, etc

x.x Name of the contact person	
x.x Address	
x.x Telephone number	
x.x Fax number	
x.x E-mail	
Sponsor status	
xx Commercial	
xx Non-commercial	
Part X: Investigator's details	
National principal investigator/principal and/or co-investigator	
X.x Name	
X.x Qualification (MD, dentist, …)	
X.x Professional address[3]	
X.x Telephone number	
X.x Fax number	
X.x E-mail	
International principal investigator (if applicable)	
4.x Name	
4.x Qualification (MD, dentist, …)	
4.x Professional address[6]	
4.x Telephone number	
4.x Fax number	
4.x E-mail	
Sub-investigator (if applicable)	
4.x Name	
4.x Qualification (MD, dentist, …)	
4.x Professional address[6]	
4.x Telephone number	
4.x Fax number	
4.x E-mail	
Monitor (regional, national…)	
4.x Name	
4.x Address	
4.x Telephone number	
4.x Fax number	
4.x E-mail	

Part X: Details of trialists and sites	
X.1 Details of the site(s): name, physical address, contact details, contact person including telephone and email contacts	

[3] If applicable include institution's name and department

X.x Details and evidence of the labs competences: • Name of the organisation • Department • Name of the contact person • Address • Telephone number • Fax number • E-mail	

Part x: Information on the IP(s)[4]	
<u>Status of the IP</u>	
x.x Does the IP for the trial have a registration in an African country or elsewhere?	
x.x If yes, provide the trade name, name of the marketing authorisation holder and the country that granted registration	
x.x Is registration [5]in the African continent envisioned?	
x.x IPD submitted: • Full IPD (CTD format) • Summary of product characteristics (SmPC) only	
X.X Has this IP been previously authorised in a clinical trial conducted by the sponsor in Africa? If so, provide Authority's name, date and approval number, trial title, protocol number, [national] principal investigator, and date of the final report	
<u>Description of the IP</u>	
X.X Product name[6] if applicable	
X.X ATC code if officially registered[7]	
x.x Pharmaceutical form	
x.x Paediatric formulation? Y/N	
x.x Maximum duration of treatment of a patient/participant according to the protocol	
x.x Dose allowed:	

[4] Please present this information for each and all investigational medicinal products to be used in the trial
[5] If more than one IMP is being tested, indicate for which IMPD registration is envisioned
[6] To be provided only when there is no trade name. This is the name routinely used by a sponsor to identify the IMP in the CT documentation (protocol, IB…).
[7] Available from the Summary of product characteristics

• 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	
x.x Estimated quantity of IMP required for the trial (including overage[8])	
x.x Route of administration	
x.x Name of each active substance (INN[9] or proposed INN if available)	
x.x Strength (specify all strengths to be used): • Concentration unit • Concentration type (exact number, range, more than, or up to) • Concentration (number)	
Type of IMP	
Is the IMP a: • Immunological medicinal product (vaccine, allergen, immune serum) • Plasma derived medicinal product • Recombinant medicinal product • Radiopharmaceutical medicinal product • Herbal medicinal product • Other, specify	

General information on the trial

Part X: Medical condition or disease under investigation	
X.X Medical condition/disease to be investigated; discuss the local epidemiology	
X.X Therapeutic area	

Part X: Trial type	
x.x Human pharmacology (Phase I) First-in-humans Bioequivalence Other, specify	
x.x Therapeutic exploratory (Phase II)	
x.x Therapeutic confirmatory (Phase III)	
x.x Therapeutic use (Phase IV)	

[8] Provide a justification if the overage is higher than 20%
[9] International Nonproprietary Names

Part xx Current workload of the investigator(s)

Provide the number of studies currently undertaken by the trialist(s) as principal and/or co-investigators, and the total number of patients participating in these studies. Present the commitments of the researcher(s) in relation to the work related to clinical trials and to other activities.

Recommended format for response:

Investigator (Name and designation)			
Total number of trials currently undertaken by the investigator	Number	Date of commencement: Expected date of completion of study:	
Total number of patients/participants for which the principal investigator is responsible on specified date	Number	Date	
Estimated time per week [168 hours denominator]		**Hours**	**%**
Clinical trials	Clinical work (patient contact)		
	Administrative work		
Organisation (Practice/University/employer)	Clinical work		
	Administrative work		
Teaching	Preparation/evaluation		
	Lectures/tutorials		
Writing up work for:			
Publication/presentation			
Reading /sourcing information			
Other (specify)			

Annex 1

Standardised wording to be added to the patient information leaflet **(PIL)**
If you have questions or concerns about this trial, you can discuss them first with your doctor or the Ethics Committee (contact details as provided on this form). If you do not receive satisfactory answers from either of them contact the Regulatory Authority at: Medicines Regulatory Medicines [Insert Contact Details]

Annex 3

Declaration by co- and principal investigator
Name: **Title of the Trial:** **Protocol No:** **Version No:** **Date of the Protocol:** **Investigational medicinal product:** **Site**:
1. I have read and understood the duties and responsibilities of the investigator as outlined in the guidelines for good clinical practice guideline ICHE6R2 or as last amended ==> we could refer to any guideline from WHO if applicable 2. I have notified the Regulatory Authority of any aspects of the above guideline with which I do not / am unable to comply. If applicable, attach it to this declaration 3. I have thoroughly read, understood, and critically analysed the protocol and all applicable documentation, including the investigator's brochure, patient information leaflet(s)/package insert and the informed consent form(s) 4. I will conduct the trial as specified in the protocol 5. To the best of my knowledge, I have the potential at the site(s) I am responsible for, to recruit the required number of suitable participants within the stipulated time period 6. I will not commence with the trial before the relevant ethics committee(s) and the Regulatory Authority provide written authorisation 7. I will obtain informed consent from all participants or from their legal representatives if they are not legally competent 8. I will ensure that every participant shall at all times be treated in a dignified manner and with respect including relatives 9. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me during the conduct of this clinical trial *[Conflict of interest exists when an investigator (or the investigator's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions.]** *Modified from: Davidoff F, *et al.* Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001) 10. I have* / have not (delete as applicable) previously been the principal investigator at a site which has been closed due to failure to comply with Good Clinical Practice *attach details 11. I have* / have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices *attach details 12. I will submit all required reports within the stipulated timeframes
Signature: Date:
Witness: Date

Annex 4

Joint declaration by the sponsor (or representative) and the national principal investigator (or principal investigator) concerning sufficient funds to complete the trial
Title of the Trial: Protocol No: Version No: Date of the Protocol: Investigational medicinal product:
I, <full name>, representing <sponsor or representative) And I, <full name>, National Principal Investigator/Principal Investigator Hereby declare that sufficient funds have been made available to complete the above-identified trial. Signed: Date: Sponsor (or representative) Name: Address: Contact details: Signed: Date: National principal investigator (or principal investigator) Name: Address: Contact details:

Annex 5

Provisional declaration by sub-investigators and other staff involved in the clinical trial
Name: Title of trial: Protocol: Version No: Date of Protocol: Study investigational medicinal product: Principal investigator's name: Site: Designation:
1. I will carry out my role in the trial as specified in the protocol 2. I will not commence with my role in the trial before written authorisations from the relevant ethics committee(s) as well as from the Regulatory Authority) have been obtained 3. If applicable to my role in the trial, I will ensure that informed consent has been obtained from all participants, or from their legal representatives if they are not legally competent 4. I will ensure that every participant shall at all times be treated in a dignified manner and with respect including relatives 5. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. *[Conflict of interest exists when an investigator (or the investigator's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions.]** *Modified from: Davidoff F, *et al.* Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001) 6. I have* /have not (delete as applicable) previously been involved in a trial which has been closed due to failure to comply with Good Clinical Practice **attach details* 7. I will submit all required reports within the stipulated timeframes
Signature: Date:
Witness: Date:

Annex 6

Declaration by the regional monitor	
Name: Title of the trial: Protocol No: Version No: Date of Protocol: Study investigational medicinal product: Principal investigator's name: Site: Designation:	
1. I have read and understood the duties and responsibilities of the monitor as outlined in the guidelines for good clinical practice guideline ICHE6R2 or as last amended 2. I have notified the regulatory authority of any aspects of the above guidelines with which I do not / am unable to, comply. If applicable, this may be attached to this declaration. 3. I will carry out my responsibilities as specified in the trial protocol and according to all applicable guidelines 4. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial [*Conflict of interest exists when an investigator (or the investigator's institution), has financial or personal relationships with other persons or organizations that inappropriately influence (bias) his or her actions*.]* *Modified from: Davidoff F, et al. Sponsorship, Authorship, and Accountability. (Editorial) JAMA Volume 286 number 10 (September 12, 2001) 5. I have* / have not (delete as applicable) previously been the monitor at a site which has been closed due to failure to comply with Good Clinical Practice *Attach details 6. I have* / have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices *attach details 7. I will submit all required reports within the stipulated timeframes	
Signature:	Date:
Witness:	Date:

Annex 7

WORDING FOR THE SPONSOR INDEMNIFICATION FOR SITES AND INVESTIGATORS

In consideration of the {PI's / Institution's / Research Unit's] participation in the study, we shall indemnify and hold harmless [Name of PI / Institution / Research Unit] and its employees from any legal liability for costs or damages for death or personal injury which may result from the administration of [Name of compound] pursuant to the said study. This indemnity does not apply to the extent that such death or personal injury arises out of any negligent act, default or omission of [Name of PI / Institution / Research Unit] or its employees. Furthermore, this indemnity is subject to the condition that the study is carried out in accordance with the Protocol approved by us in writing, that [Name of Sponsor] is notified immediately on receipt of any claim, that [Name of Sponsor] shall have full control of the management and defence of any such claim and that no offer to compromise or settle any claim is made without the written agreement of [Name of Sponsor].

Note: The wording for Sponsor Indemnification for investigators and sites serves as a guide and is not an exclusive approach.

Update history

Date	Reason for the update	Version & publication
May 2003	First version published for implementation	Version 1, May 2003
April 2017	Revised version published for implementation	Version 2, October 2017