CLINICAL TRIAL APPLICATION CHECKLIST

African Vaccine Regulatory Forum (AVAREF)

Clinical trial application checklist

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

Version	Date	Comments
Version 1	September 2018	Endorsed by Avaref's steering committee in Entebbe, Uganda,
Version 2	October 2019	To be tabled for adoption at the Avaref Assembly in Victoria Falls, Zimbabwe

CLINICAL TRIAL APPLICATION CHECKLIST

Checklist

No.	Item
1.	☐ Cover letter including list of documents submitted and their version number and date
2.	☐ Completed clinical trial application form including cover page
3.	☐ Clinical trial protocol including site specific addendums
4.	☐ Informed consent form(s)
5.	☐ Product information if the investigational medical product is registered: summary of product characteristics, patient information leaflet/package insert, and labelling
6.	☐ Investigator's brochure
7.	☐ If applicable, synopsis of previous trials with the investigational medical product(s)
8.	☐ If applicable, electronic copies of key peer reviewed publications following ICMJE recommendations to support the application
9.	☐ Copy/ies of recruitment advertisement(s) (if applicable) and questionnaires
10.	☐ Investigational medical product dossier[1] (If applicable)
11.	☐ Product information and certificate of analysis for the concomitant and rescue medications
12.	☐ GMP certificate for the site(s) producing the IMP(s)[2]
13.	☐ Certificate(s) of analysis of the IMP(s)
14.	☐ Certificate(s) of accreditation for the central laboratories
15.	☐ Signed declaration by the applicant
16.	☐ Signed declaration by the national principal investigator
17.	☐ Workload forms for investigators
18.	☐ Signed curriculum vitae[3] for all key staff participating in the conduct of the clinical trial, eg national principal investigator, principal and/or co-investigators, study coordinator, regional and local monitor, contract research affiliate, etc
19.	☐ Signed declaration(s) by each investigator(s)[4]
20.	☐ Signed joint financial declaration between the sponsor and the national principal investigator
21.	☐ Signed declaration by the sub-investigators and key staff participating in the clinical trial
22.	☐ Signed declaration by the regional monitor(s)
23.	☐ Proof of registration on PACTR or other WHO primary accessible registry
24.	☐ Active clinical trials insurance (Phase I, II, III)
25.	☐ Proof of sponsor indemnification for investigators and trial site
26.	☐ GCP certificates for the investigators
27.	☐ Proof of registration of the key investigators with a professional statutory body (if applicable)

[1] This is not required if the investigational medical product was granted registration by a stringent regulatory authority and will be used as defined therein, or if the investigational medical product is prequalified by the WHO. Of note, the WHO is leading a process to change the term stringent reference authority to WHO listed authorities. The term will be added to this document once the WHO completes the process

[2] Investigational medical product and placebo

[3] Curriculum vitae to be submitted in the format provided in Annex 8 of the "Clinical trial application form"

[4] They could include the national principal investigator, or principal investigator and co-investigator as applicable. Each investigator is expected to sign and date one form. The form is provided in Annex 3

28.	☐	Proof of professional indemnity (malpractice insurance)
29.	☐	Study budget
30.	☐	Favourable opinion of the Ethics Committee
31.	☐	Data Safety Monitoring Board charter and composition (where applicable)

NB: Incomplete documentation or sub-standard submissions will be rejected. The application should be ring-bound. Lever arch files will not be accepted.