TITLE: APPLICATION FORM FOR CONDUCTING CLINICAL TRIALS

CHECKLIST FOR SUBMISSION OF CLINICAL TRIALS APPLICATION TO THE FDA

Applicant's Check	Requirements	%	FDA's Check
	Covering Letter	**20**	
	Fees / Proof of payment	**20**	
	Clinical Trial Application Form	**4**	
	Trial Protocol (including Informed Consent Forms)	**20**	
	Investigational Product Information: □ Investigator's Brochure / SmPC □ Report / Summaries of prior clinical trials with the IP □ Certificate of GMP manufacture of the trial medicines □ Package Insert/s for other trial medicines □ Certificate of GMP manufacture of the placebo /comparator - if appropriate	**10**	
	Evidence of accreditation of the designated laboratories		
	Insurance Certificate specific for the trial	**5**	
	Signed and completed Declarations by Investigators	**4**	
	Ethics Committee's approval of the Protocol	**10**	
	Full, legible copies of key, peer-reviewed published articles supporting the application		
	Other appended documents	**4**	
	Financial Declaration	**3**	
	TOTAL weighted submission	**100**	

** At least 70% of the requirements for a Clinical Trial Application must be available at the time of submission for the application to be accepted for processing.

Note:

i. *Summarized review comments on this Clinical Trial Application shall be published on the Clinical Trial Registry on the Authority's website. This is to ensure transparency. However, critical information regarding the trial shall be treated with strict confidentiality.*
ii. *Relevant portions of this application form may be photocopied and used if necessary.*

1. ADMINISTRATIVE DETAILS

a) Particulars of applicant

If an individual:

Full name ……

Qualifications……

Postal Address ……

……

……

Telephone number ……

Fax……

E-mail ……

If an institution:

Name of institution ……..

Postal Address……

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……..

Telephone Number……

Fax……

E-mail……

Name and status of person in the company making the application on behalf of the company……

b) Sponsor(s) details:

Name……

PostalAddress……..

……..……..

……

Telephone Number……Fax……..……

E-mail……

Name of Contact Person(s)…….....

Postal Address: ……..

……

……

Telephone Number……

Fax……..……...

E-mail: ...……...

c) Principal Investigator(s) details:

Name of Principal Investigator(s)……..

Registration No (If applicable): ……

Postal Address: ……...

……

Telephone Number……

Fax……..……...

E-mail: ……..……

Name of Principal Investigator(s) ……

Registration No. (If applicable): ……

Postal Address: ……...

Telephone Number……

Fax……..……...

E-mail: ……..

d) Monitor(s) details

Independent Monitor's name ……

Postal Address: ……...

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Telephone Number……..

Fax……..……...

E-mail: ……..

Local Monitor's name ……

Postal Address: ……...

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Telephone Number……

Fax……..……...

E-mail: ……..

e) Pharmacist(s) details

Name: ……...

Registration No: ……..

Postal Address: ……...

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Telephone Number……

Fax……..……...

E-mail: ……..

2. TRIAL DETAILS

a) Study title and acronym

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b) Clinical Trial Registration Number i.e. PACTR reference number (including any other additional international trial identifiers if available): ……

c) Phase of trial (e.g phase 1): ……..

d) Proposed date of commencement of trial: ……..

e) Proposed date of completion of trial: ……..

f) Name(s) of Trial Centre(s): ……...

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g) Location of Trial Centre(s):

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h) Number of participants expected to take part in the study:

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3. DETAILS OF INVESTIGATIONAL PRODUCT(S)

a) Brand Name of Investigational Product:……..

……..

b) Generic Name of Investigational Product:……...

……..

c) Dosage Form: ……

d) Route of Administration: ……..……..

e) Dosing……

……..

……,……

f) Details of control (Name, dosage form, route of administration, dosing etc):

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g) Indicate whether any other drug will be given concomitantly. YES/NO*

If YES, state the name of the drug ……..

h) State the total quantities of all investigational products including products for control group(s) that would be required for the full conduct of the study

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i) Attach the label and package insert of investigational product if product has already been registered for use in Ghana.

j) State any adverse or possible reactions to the product

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k) Has the drug been registered in the country of origin? YES/NO

If YES a valid certificate of registration in respect of such drug issued by the appropriate authority established for the registration of drugs in the country of origin shall accompany this application.

If NO state details ……

l) Have clinical trials been conducted in the country of origin? YES/NO

If YES state details: ……

If NO, give reasons why: ……

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m) Has the drug been registered for use in Ghana? YES/NO

n) Has the drug been registered in any other country? YES/NO

If YES state details: ……

o) Has an application for registration of the drug been made in any other country? YES/NO

If YES, state details including the date on which the application was lodged

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p) Has the registration of the drug been rejected, or refused, deferred or cancelled in any country? YES/NO

If YES, state details ……

Current work-load of Investigator(s): Number of studies currently undertaken by trialist(s) as principal and/or co-investigators, and the total number of patients/ represented by these studies. Time-commitments of the researcher(s) in relation to clinical work and non-trial work

Recommended format for response:

Investigator (Name and designation)		
Total number of studies being currently undertaken by the investigator	Number	Date of commencement: Expected date of completion of study:

Total number of patients /participants for which PI is responsible for on specified date	Number	Date	
ESTIMATED TIME PER WEEK [168 hours denominator]		**Hours**	**%**
Clinical trials	Clinical work (patient contact)		
	Administrative work		
Organization (Practice/University/employer)	Clinical work		
	Administrative work		
Teaching	Preparation/evaluation		
	Lectures/tutorials		
Writing up work for publication/presentation			
Reading /sourcing information (e.g. Internet searches)			
Other (specify)			

Declaration

I/We the undersigned, hereby declare that all information contained herein is correct and true.

Sponsor's name/ Authorized Person: ……..

Authorized signature: …….

Date: …….