KENYA: CLINICAL TRIAL APPLICATION FORM

To be completed by the Sponsor or Sponsor's representative.
(To be submitted along with the necessary protocol as indicated in the GUIDELINES FOR APPLICATIONS TO CONDUCT CLINICAL TRIALS IN KENYA.)

Study Title:

Protocol No:

Version No: Date of Protocol:

Study Drug:

ECCT Ref number (if applicable):

Sponsor:

Contact Person:

Address:

Telephone Number: Fax Number:

Cell Number: E-mail address:

TICK AND PROVIDE NECESSARY DETAILS AS APPROPRIATE

2. NUMBER OF SITES

Single site in Kenya : yes ☐ no ☐

If yes, name of site……

Multiple sites in Kenya : yes ☐ no ☐

Number of sites anticipated in Kenya ( )

If yes list the sites……

Multiple countries: yes ☐ no ☐

Number of states anticipated in the trial ( )

If yes above list the countries……

Does this trial have a data monitoring committee?	yes ☐ no ☐

3. PARTICIPANTS (SUBJECTS)

3.1 Number of participants in Kenya:

3.2 Total enrolment in each Kenyan site: (if competitive enrolment, state minimum and maximum number per site.)

3.3 Total participants worldwide:

4.0 AGE SPAN

Less than 18 years	yes ☐ no ☐
If yes specify:	
In Utero	yes ☐ no ☐
Preterm Newborn Infants (up to gestational age < 37 weeks)	yes ☐ no ☐
Newborn (0-28 days)	yes ☐ no ☐
Infant and toddler (29 days - 23 months)	yes ☐ no ☐
Children (2-12 years)	yes ☐ no ☐
Adolescent (13-17 years)	yes ☐ no ☐
18 years and over	yes ☐ no ☐
Adult (18-65 years)	yes ☐ no ☐
Elderly (> 65 years)	yes ☐ no ☐

5.0 GROUP OF TRIAL SUBJECTS

Healthy volunteers	yes ☐ no ☐
Patients	yes ☐ no ☐
Specific vulnerable populations	yes ☐ no ☐
Women of child bearing potential	yes ☐ no ☐
Women of child bearing potential using contraception	yes ☐ no ☐
Pregnant women	yes ☐ no ☐
Nursing women	yes ☐ no ☐
Emergency situation	yes ☐ no ☐
Subjects incapable of giving consent personally	yes ☐ no ☐

If yes, specify :

Others : yes ☐ no ☐

If yes, specify

6.0 GENDER

Female	☐
Male	☐

7.0 CO-ORDINATING INVESTIGATOR (*for multicentre trials in Kenya*)

Given name

Middle name, if applicable

Family name

Qualification

Professional address:

8.0 PRINCIPAL INVESTIGATOR *(for multicentre trial ; where necessary, use additional forms)*

Given name

Middle name, if applicable

Family name

Qualification

Professional address

9.0 ORGANISATIONS TO WHOM THE SPONSOR HAS TRANSFERRED TRIAL RELATED DUTIES AND FUNCTIONS (repeat as needed for multiple organisations)

Has the sponsor transferred any major or all the sponsor's trial related duties and functions to another organisation or third party? yes ☐ no ☐

Repeat as necessary for multiple organisations:

Organisation :

Name of contact person :

Address :

Telephone number :

All tasks of the sponsor	yes ☐ no ☐
Monitoring	yes ☐ no ☐
Regulatory (e.g. preparation of applications to CA and ethics committee)	yes ☐ no ☐
Investigator recruitment	yes ☐ no ☐
IVRS – treatment randomisation	yes ☐ no ☐
Data management	yes ☐ no ☐
E-data capture	yes ☐ no ☐
SUSAR reporting	yes ☐ no ☐
Quality assurance auditing	yes ☐ no ☐
Statistical analysis	yes ☐ no ☐
Medical writing	yes ☐ no ☐
Other duties subcontracted	yes ☐ no ☐

If yes to other please specify:

10.0 PRINCIPAL INCLUSION CRITERIA

List them here;

11.0 PRINCIPAL EXCLUSION CRITERIA
List them here;
12.0 PRIMARY END POINT(S) :
List them here;
13.0 SCOPE OF THE TRIAL – Tick all boxes where applicable
Diagnosis ☐
Prophylaxis ☐
Therapy ☐
Safety ☐
Efficacy ☐
Pharmacokinetic ☐

Pharmacodynamic	☐
Bioequivalence	☐
Dose Response	☐
Pharmacogenetic	☐
Pharmacogenomic	☐
Pharmacoeconomic	☐
Others	☐
If others, specify:	

14.0 TRIAL TYPE AND PHASE

Human pharmacology (Phase I)	☐
Is it:	
First administration to humans	☐
Bioequivalence study	☐
Other :	☐
If other, please specify	
Therapeutic exploratory (Phase II)	☐
Therapeutic confirmatory (Phase III)	☐
Therapeutic use (Phase IV)	☐

15.0 DESIGN OF THE TRIAL

Controlled If yes, specify:	yes ☐ no ☐
Randomised	yes ☐ no ☐
Open :	yes ☐ no ☐
Single blind :	yes ☐ no ☐
Double blind:	yes ☐ no ☐
Parallel group:	yes ☐ no ☐
Cross over :	yes ☐ no ☐
Other : If yes to other specify: If controlled, specify the comparator:	yes ☐ no ☐
Other medicinal product(s)	yes ☐ no ☐
Placebo	yes ☐ no ☐
Other	yes ☐ no ☐

If yes to other, specify :

16.0 INFORMATION ON PLACEBO (if relevant; repeat as necessary)

Is a there a placebo:	yes ☐ no ☐

Pharmaceutical form :

Route of administration :

Composition, apart from the active substance(s):

Is it otherwise identical to the INDP?	yes ☐ no ☐

If not, specify major ingredients :

17.0 Details of Site(s)
Name of site Physical address Contact details Contact person
18.0 Capacity of Site(s):
Number of staff, names, qualifications, experience -- including study co-ordinators, site facilities, emergency facilities, other relevant infrastructure)

19.0 OTHER DETAILS

19.1 If the trial is to be conducted in Kenya and not in the host country of the applicant / sponsor, provide an explanation:

19.2 Estimated duration of trial:

19.3 Name other Regulatory Authorities to which applications to do this trial have been submitted, but approval has not yet been granted. Include date(s) of application:

19.4 Name other Regulatory Authorities which have approved this trial, date(s) of approval and number of sites per country:

19.5 If applicable, name other Regulatory Authorities or Ethics Committees which have rejected this trial and give reasons for rejection:

19.6 If applicable, details of and reasons for this trial having been halted at any stage by other Regulatory Authorities: