Application form for clinical trial authorization in Mali

This form includes three (03) parts.

era 1 part: LETTER OF REQUEST ADDRESSED TO THE MINISTER OF HEALTH

Name and full address of the clinical trial authorization applicant *(to be specified)*

Place and date *(to be specified)*

AT

Minister of Health and public hygiene
C/S
Department of Pharmacy and Medicine

Minister,

I have the honor to request from your great benevolence, the authorization to carry out in Mali, the clinical study entitled:

…….. *(Full title of the study)* …… .

The file includes the following parts: confers checklist.

It includes two copies in paper format and one copy in electronic format *(specify :* CD-room or USB key).

Please accept, **Minister,** the assurance of my highest consideration.

Signature

Last name and first names)

2th part: ADMISSIBILITY AND RECEIPT OF THE APPLICATION FILE

(To be completed by the applicant and the DPM)

Section 1: CHECKLIST: Please tick the appropriate box

APPLICANT **Verification**		*DPM* **Re-verification**
☐	**COMPLETED CLINICAL TRIAL AUTHORIZATION APPLICATION FORM AND SIGNED BY THE PROMOTER**	☐
☐	**COPIES OF IMPORT AND/OR EXPORT REQUESTS FOR PRODUCTS**	☐
☐	**CLINICAL TRIAL PROTOCOL IN FRENCH**	☐
☐	**INVESTIGATORS BROCHURE**	☐
☐	**CURRICULUM VITAE SIGNS OF THE INVESTIGATOR(S)**	☐
☐	**PARTICIPANT INFORMATION NOTE/FLYER**	☐
☐	**INFORMED CONSENT FORM**	☐
☐	**CERTIFICATE(S) OF GOOD MANUFACTURING PRACTICES FOR PRODUCTS ISSUED BY ANRP IN THE COUNTRY OF MANUFACTURE *(Clinical trial product, Placebo, comparator product, other products used in the clinical trial)***	☐
☐	**ESTABLISHMENT OPENING CERTIFICATES AND/OR MANUFACTURING AUTHORIZATION MANUFACTURING LABORATORIES ISSUED BY THE REGULATORY AUTHORITY PHARMACEUTICALS OF THE COUNTRY OF MANUFACTURE**	☐
☐	**UPDATED AND VALID CERTIFICATE OF INSURANCE FOR CLINICAL TRIAL**	☐
☐	**DECLARATION FORMS COMPLETED AND SIGNED BY THE INVESTIGATOR(S)**	☐
☐	**PROOF OF APPROVAL OF THE CLINICAL TRIAL PROTOCOL BY THE ETHICS COMMITTEE FOR HEALTH RESEARCH IN MALI**	☐
☐	**SUPPORTING DOCUMENTS FOR PAYMENT OF FILE FEES**	☐
☐	**OTHER PARTS OR DOCUMENTS PROVIDED (specify)** *1. …… ……* *2. …… ……*	☐
☐	**PAPER VERSION AND ELECTRONIC VERSION (……. USB keys, ……. CD-room) OF THE FILE**	☐

Section 2: *Reception* (To be completed by the research and evaluation section of the DPM)

Date/ time of receipt of the application file: File number: Name of the recipient of the application ……

file: Signature of the recipient of the application: Date of request for additional information : ……

Dates of receipt of the additional information requested: Opinion of the Technical Committee: …….. Date: …… ……

Other information : ……

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3th part: INFORMATION (To be completed by the applicant)

Section 1: Administrative information

A. Responsible Promoter

Individual/Company/Institution/Organization:		Company code if known:	
Address (Street/Office/PO box):			
City :	Province/Region/State:	Country :	Zip/postal code:

Information on the promoter (if the promoter is an individual) or the senior official (if the promoter is a company, an institution or an organization)

☐ Mr. ☐ Mrs. ☐ Dr. ☐ Pr	Name :	First name :
Title :		Correspondence language : ☐ English ☐ French
Phone Number :	Fax number:	Email address :

B. Representative of the promoter in Mali (if the promoter does not reside in Mali)

☐ Mr ☐ Mrs ☐ Dr. ☐ Pr	Name :	First name :
Title :		Correspondence language : ☐ English ☐ French
Company Name :		The address is identical to that of the promoter: ☐ Yes ☐ No
Address (Street/Office/PO Box):		
City :	Province/Region/State:	Country : / Zip/postal code:
Telephone No.: Fax No.:		Email address :

Section 2: information relating to each product used in the clinical trial

A. Product studied (repeat the section as many times as necessary, in the case where there are several products under study)

The studied product is ?

☐ a drug :
- ☐ of homeopathic
- ☐ chemical origin
- ☐ derived from blood
- ☐ immunological (vaccine, immunoserum) based
- ☐ on plants of animal origin
- ☐ of biotechnological origin
- ☐ radiopharmaceutical

☐ a reagent

☐ a medical device

☐ a particular foodstuff

☐ Other (explain, list) :

Does the product studied have an MA in Mali? ☐ Yes ☐ No

If yes, give the MA references or a copy of the MA:

Designation (code if appropriate): INN:

Name of marketing authorization holder:

Does the product studied have an MA in other countries? ☐ Yes ☐ No

If yes, list the main countries:

The file of the studied product provided is: -
- complete - ☐ Yes ☐ No
- simplified the ☐ Yes ☐ No
- summary of product characteristics (RCP) ☐ Yes ☐ No

B. Comparator/reference product (if applicable)

Does the comparator product have an MA in Mali? ☐ Yes ☐ No

If yes, give the MA references or a copy of the MA:

Proprietary name: INN: Name of the MA holder: Does the comparator product have a MA in other countries If yes, list the main countries: ☐ Yes ☐ No

The dossier for the product studied provided is: - complete - simplified - summary of product characteristics (RCP)
- ☐ Yes ☐ No
- ☐ Yes ☐ No
- ☐ Yes ☐ No

C. PLACEBO (repeat section as many times as needed, if applicable)

Is a placebo used in the trial? ☐ Yes ☐ No

If yes, pharmaceutical form and route of administration: Is the placebo identical to the experimental drug studied? ☐ Yes ☐ No

If not, specify the main components:

Section 3: Information on investigators in Mali

Coordinating investigator (if multicenter study) or Principal investigator (if monocentric study)

☐ Mr ☐ Mrs ☐ Dr. ☐ Pr ☐	Name :	First name :
Qualifications, specialty:		Correspondence language : ☐ English ☐ French
Address :		
Phone Number :	Fax number	Email address :

Section 4: Information on the study site(s)

☐ Monocentric national study ☐ National multicenter study
☐ Multicenter international study

In the case of a multicenter study, specify the total number of sites:

In the case of an international study, specify the other countries where it is carried out:

Total number of sites for the clinical trial in Mali:

Coordinating center or investigating center in Mali:

Section 5: Information about study participants

Total number of participants to recruit in Mali: Total number of participants to recruit worldwide: Number of patients to recruit in Mali:

Number of healthy volunteers to be recruited in Mali:

Does the study involve? ☐ infants and/children ☐ pregnant and/or ☐ breastfeeding women ☐ women of childbearing age? ☐ sick volunteers?

Section 6: Information on the opinion of the National Ethics Committee for Health Research

Is the certificate of approval of the national ethics committee for health research of Mali provided accompanied by remarks or recommendations? ☐ Yes ☐ No

If yes, specify:

Has this request received an unfavorable ethical opinion in another country? ☐ Yes ☐ No

If yes, name the countries and provide the main reasons:

Section 7: Clinical Trial Information

A. Identification of the clinical trial

Full title:

Name and short title if applicable:

Protocol identification number: Protocol date: Version number:

Registration references in PACTR:

Registration references in other international registers:

Is it: ☐ a new request? a modification of a request? ☐

☐ a re-submission of the application? ☐ Other :

B. Scope and type of study

Does the clinical trial application concern? ☐ Bioequivalence/Biavailability

☐ Diagnosis prophylaxis If therapeutic ☐ Therapeutic ☐ Other (explain, list) :

specify if: ☐ Phase I ☐ Phase II ☐ Phase III ☐ Stage IV

C. Regulatory aspects

Has the trial already received ANR approval from other countries? ☐ Yes ☐ No

If yes, which ones ?

Has this trial already been rejected, postponed or stopped by an ANR from another country? ☐ No

Yes If yes, name the countries and provide the main reasons:

Section 8: Proponent Commitment

I hereby certify that:

- the information provided above in support of the request is accurate;
- the test will be carried out in accordance with the protocol, the regulations of Mali and the principles of good clinical practice.

I also undertake to:

- to declare unexpected serious adverse effects and to submit reports of safety, in accordance with the regulations in force in Mali,
- submit a summary of the final report of the clinical trial to the DPM, at the latest one (01) year after the end of the trial.

Last name and first name(s) of the promoter **Signature** **Date**