RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department
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RWANDA FDA Rwanda Food and Drugs Authority	Title: **SCREEING AND RECORDING CLINICAL TRIAL APPLICATIONS**	Revision Number : 0 Revision Date: : 26 February 2021 Effective Date : 01 March 2021 Review Due Date : 01 March 2023

RWANDA FOOD AND DRUGS AUTHORITY STANDARD OPERATING PROCEDURE (SOP) ON SCREEING AND RECORDING CLINICAL TRIAL APPLICATIONS

	Author	Checked by			Authorized by	
Title	**Clinical Trial Specialist**	**Division Manager PV-SM**	**Head od Department of FDISM**	**Quality Management Systems**	Director General	Page 1 of 16
Signature & Date						

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1.0 PURPOSE

1.1 This standard operating procedures (SOPs) describe the procedures for Screening and recording New Clinical Trial Applications and Application for amendments of an approved clinical trials submitted to Rwanda FDA

1.2 Ensure the overall consistency and compliance with regulatory requirements as stipulated in relevant regulations and guidelines for clinical Trials

2.0 SCOPE

The SOP is applicable to all Clinical Trial new applications and applications for amendments of an already approved clinical trial (substantial and non-substantial amendments) submitted to Rwanda FDA, It doesn't apply to the additional data submitted during the assessment of clinical trial or amendments.

4.0 DEFINITIONS AND ABBREVIATIONS

4.1 DEFINITIONS

4.1.1. Amendments: A written description of a change(s) to or formal clarification of a Clinical Trial protocol that has already approved by the authority

4.1.2. **Substantial: amendment**: changes to the terms of the protocol or any other trial supporting documentation that is likely to have significant impact and affect the safety and integrity of trial participants, the scientific value of the research, the conduct or management of the research, and the quality or safety of any investigational medicinal product used in research.

4.1.3. **An-substantial amendments**: changes to the details of a trial study which have no significant implications for the study participants, conduct, management and scientific value of the research

4.2 ABBREVIATIONS:

CTA: Clinical Trial Application

CTAA: Clinical Trial Application for Amendment

FIFO: First in First Out

SOPs: Standards Operating Procedures

Rwanda FDA: Rwanda Food and Drugs Authority

5.0 RESPONSIBILITY

5.1 The Director General is responsible for the overall approval or rejection of Clinical Trials applications

5.2 Head of department of Food & Drugs Inspection and Safety Monitoring are responsible for:

a) Ensuring that this SOP is correctly and consistently implemented during the process of review of application for amendment of an approved clinical trial and amendments

b) Reviewing and providing regulatory guidance on draft feedbacks (additional data requests, approval letters) according to the outcome of the assessment

c) Monitoring and evaluation of Clinical Trial applications

d) Ensuring that this SOP is regularly updated.

5.3 Clinical Trial Analyst and Clinical Trial Specialists are responsible for:

a) Becoming fully familiar with screening and recording procedures for clinical trial applications, including trial amendments
b) Complying with this SOP whenever carrying out screening of Clinical Trial (CTA)application for amendment of an approved clinical trial (CTAA)
c) Record the CTAs and CTA-As in Clinical Trial Application Database
d) Screen submitted Clinical Trial Aapplications CTAs and amendments (CTA-As) for completeness according to the regulations and requirements using first in First out (FIFO) rules
e) Writing screening report of CTAs and CTA-As and prepare draft feedbacks (Request for Clarification or acknowledgement letter) according to the outcome of the screening
f) Ensuring that this SOP is regularly updated.

6.0 DISTRIBUTION

6.1 Heads of Department of Food and Drugs Inspection and Safety Monitoring
6.2 Division Manager of Pharmacovigilance & Safety Monitoring,
6.3 Clinical Trial Analyst
6.4 Clinical Trial specialists
6.5 In charge of Quality Management System

7.0 REFERENCE

NA

8.0 SAFETY PRECAUTIONS

NA

9.0 MATERIALS AND EQUIPMENT

9.1 An electronic copy of the Clinical Trial Application for amendments

9.2 Guidelines No DIS/GDL/033 Rev Nº 0 for Clinical Trial Application and its annexes

9.3 Rwanda FDA regulations No CBD/TRG/015 Rev 0 governing Clinical Trials in Rwanda

9.4 Regulations No CBD/TRG/004 Rev No 1: Related to the regulatory services tariff/fees and fines

9.5 Screening and Assessment templates

10.0 PROCEDURES

10.1. SCREENING AND RECORDING OF CLINICAL TRIAL APPLICATIONS

10.1.1 Retrieve the screened Clinical Trial Application (CTA) or amendment (CTAA) and Screening Report template

10.1.2 Save on your PC and give it a name corresponding to the CTA or CTA-A file number, e.g. for **XX-CTA-2021-RwandaFDA or XX-CTAA-2021-RwandaFDA.**

10.1.3 Update the Clinical Trial Applications database

10.1.4 The database shall include at least the following elements (Date of application, Reference Number, Title of the clinical trial, Name of Sponsor, Contract Research Organization (CRO), Principal Investigator (PI), Name of the Investigational Products, Trial Phase, Trial sites,)

10.1.5 Screening the application for completeness and compare submitted dossiers with Rwanda FDA requirements and regulations within 2 calendar days.

10.1.6 Prepare Request for Clarification in case of deficiencies or acknowledgement letter if the application meets Rwanda FDA requirements

10.1.7 In the assessment report, the comments should be typed with "Times New Roman 12" fonts and comments should be introduced in RED font.

10.1.8 The proposed points to be communicated with the applicant as Request for Clarification shall be highlighted in YELLOW.

10.1.9 Save the final Screening report together with applications and draft deficiencies or acknowledged letter.

10.2 NOTIFICATION OF SCREENING OUTCOME

10.2.1 After completion of screening the Clinical Trial Application or Amendments, requests for Clarification during screening or acknowledgement notification should be provided within 2 calendar days.

10.2.2 Submit the folder containing screening report, Application letter, and draft requests for Clarification or acknowledgement notification as a zipped folder to the Division Manager of Pharmacovigilance and Safety Monitoring for further action.

11.0 Document Revision History

Date of revision	Revision number	Author(s)	Changes made and/or reasons for revision
16/11/2020	0	Clinical Trial Specialist	First issue

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Annexes

TEMPLATE FOR ASSESSMENT OF CLINICAL TRIAL APPLICATIONS

Date of the submission (covering letter)	
Date of receipt (Rwanda FDA stamp)	
Application Reference Number	**XX**/CTA/2021RwandaFDA.
Date of Application Screening	
Date of 1st assessment	
Date of 2nd assessment	
Type CT Application	☐ New Application ☐ Amendment Application ☐ Additional Information
Title of Clinical Trial Application	
Protocol Reference Number	
Protocol Version Number (where applicable)	
Name and complete address of CT Applicant	

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Names of Principal Investigator		
Names of Co-Investigator		
Names of Sponsor (If applicable)		
Name and address of the Contract research Organisation (s) (CRO) where the clinical studies proving efficacy and safety of the product were conducted.		
Phase of Trial (if applicable)		
Number of Participants (Trial subjects)		
Number of Clinical Trial Site.		
List of Clinical Trial Sites		
Duration of Clinical Trial		
First assessor	Name	Signature
Second assessor	Name	Signature
Name of Investigational Product (IP) Proprietary Product Name (if relevant)		
International Non-proprietary Name (INN) of the Active Pharmaceutical Ingredient (API), strength, pharmaceutical form.		

Name (s) and complete address (es) of the manufacturer (s) of the Investigational product (s), including the final product release if different from the manufacturer.	
IP Therapeutic Classification	
IP Route of Administration	
IP storage Information	
Conclusion of the CT Assessment	☐ **ACCEPTED** ☐ **ADDITIONAL DATA REQUESTED** ☐ **REJECTED**
Points to be communicated with the Clinical Trial Applicant: *Please copy all relevant information to be communicated to the CT applicant in the corresponding letter and save it accordingly*	
Clinical Trial Commitments (if any)	
General remarks to next assessors: *List issues identified during the assessment for the follow up assessment, such as information to be confirmed, to be verified, etc.*	
Recommendations to GCP Inspectors:	

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List issues identified during the CT assessment phase that require verification during a GCP inspection	

The Clinical trial assessment report should be written in clear unambiguous language referring to deficiencies or lack of data submitted, as communication with the manufacturer may result from the assessment.

- The assessment report should be typed with "Times New Roman 12" fonts. The format of tables must not be changed.
- The 1st assessor's (R1) comments should be introduced in **red**.
- The 2nd assessor's (R2) comments should be written in **blue**.
- Deficiencies should be highlighted in yellow (in either red or blue text depending) in the body of the report. The assessor should write the deficiencies in the form of a question to the applicant. The question should be written such that it can be understood without reading the assessment report.
- The R2s should not delete the comments and questions raised by the R1s. They may instead strikethrough the text. In case of a disagreement, this should be clearly indicated and a justification for the disagreement should be provided by the R2.
- At end the end of R2 reports, take all agreed points to be communicated with the Clinical Trial Applicant to the appropriate section'' point to be communicated with the applicant''.

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CLINICAL TRIAL APPLICATION (CTA) SCREENING REPORT FORM

	Clinical Trial Application Number (CTA number):	
	Clinical Trial Application (CTA) Title	
#	**CTA CHECKLIST OF REQUIRED DOCUMENTS**	
a.	**Cover letter addressed to Director General of the Authority**	☐ **Provided** ☐ **Not Provided**
	Comments:	
b.	**A duly filled and signed clinical trial application form obtained from Rwanda FDA**	☐ **Provided** ☐ **Not Provided**
	Comments:	
c.	**General investigational plan**	☐ **Provided** ☐ **Not Provided**
	Comments:	
d.	**Clinical trial Protocol (detailed content Annex 2)**	☐ **Provided** ☐ **Not Provided**
	Comments:	

e.	**Investigators' brochures**	☐ **Provided** ☐ **Not Provided**
	Comments:	
f.	**Capacity building plans including training and updating of staff involved in the trial**	☐ **Provided** ☐ **Not Provided**
	Comments:	
g.	**Clinical study reports (accomplished Clinical trial phases):**	☐ **Provided** ☐ **Not Provided**
	Comments:	
h.	**National Ethics Committee Clearance**	☐ **Provided** ☐ **Not Provided**
	Comments:	
i.	**Participant Information Leaflet (PIL).**	☐ **Provided** ☐ **Not Provided**

	Comments:	
j.	**Informed Consent Forms (English, French and Kinyarwanda)**	☐ **Provided** ☐ **Not Provided**
	Comments:	
k.	**Curriculum vitae (CVs) of Principal investigator and Co-investigators**	☐ **Provided** ☐ **Not Provided**
	Comments:	
l.	**Joint declaration by Sponsor (or representative) and National Principal Investigator in prescribed format (Annex 3)**	☐ **Provided** ☐ **Not Provided**
	Comments:	
m.	**Evidence of accreditation of the designated Laboratories or other evidence of Good Laboratory Practice (GLP) and assay validation**	☐ **Provided** ☐ **Not Provided**
	Comments:	

n.	**Letters of Access (if applicable) authorizing the Authority to access related files (Drug master, Site Reference Files) must be submitted.**	☐ **Provided** ☐ **Not Provided**
	Comments:	
o.	**Filled in Quality Overall Summary – Chemical Entities Template. (Annex 4)**	☐ **Provided** ☐ **Not Provided**
	Comments:	
p.	**Declarations by Principal investigator and Co-investigators (Annex 5)**	☐ **Provided** ☐ **Not Provided**
	Comments:	
q.	**Evidence of agreement between the Sponsor and the Investigator.**	☐ **Provided** ☐ **Not Provided**
	Comments:	
r.	**Case Report Forms (CRFs)**	☐ **Provided** ☐ **Not Provided**
	Comments:	
s.	**Serious Adverse Events reporting form (Annex 6)**	☐ **Provided** ☐ **Not Provided**

	Comments:	
t.	**Valid insurance policy cover of study participants**	☐ **Provided** ☐ **Not Provided**
	Comments:	
u.	**Certificate of Good Manufacturing Practice (GMP) for manufacture of the trial product and/or placebo**	☐ **Provided** ☐ **Not Provided**
	Comments:	
v.	**Trial product labels and package Insert/s for other trial medicines.**	☐ **Provided** ☐ **Not Provided**
	Comments:	
w.	**Mock up labels for the Investigational products.**	☐ **Provided** ☐ **Not Provided**
	Comments:	

x.	**List and Charter of the Data Safety Monitoring Board/Committee (DSMB).**	☐ **Provided** ☐ **Not Provided**
	Comments:	
y	**Declaration of Conflict of Interest, Financial Disclosure by the investigator**	☐ **Provided** ☐ **Not Provided**
	Comments:	
z	**Evidence of payment of prescribed fees for CTA or CTA**	☐ **Provided** ☐ **Not Provided**
	Comments:	

Note:

1. Certificate of Good Manufacturing Practice (GMP) for the investigational product or statement on GMP from the manufacturer/re-packer (whichever is more relevant) is required.
2. For local product, the manufacturing license is required.
3. For a comparator product, a valid GMP/ISO certificate is required. If not available, Approval letter from the competent regulatory authority or Package insert is required

4. EC approvals of study protocols should be submitted along with the CTA to the Authority