



RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Food and Drugs Inspection and Safety Monitoring Department
Document Type: <b>Standard Operating Procedure</b>			Doc. Number : <b>DIS/SOP/....</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>		Revision Number : 0
			Revision Date: : 24 February 2021
			Effective Date : 01 March 2021
			Review Due Date : <b>01 March 2023</b>

**RWANDA FOOD AND DRUGS AUTHORITY STANDARD OPERATING  
PROCEDURE (SOP) ON REVIEW OF APPLICATION FOR  
AMENDMENT OF AN APPROVED CLINICAL TRIAL**

	Author	Checked by			Authorized by	Page 1 of 19
Title	<b>Clinical Trial Specialist</b>	<b>Division Manager PV-SM</b>	<b>Head of Department of FDISM</b>	<b>Quality Management Systems</b>	Director General	
Signature & Date						

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>			Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0	
		Revision Date: : 24 February 2021	
		Effective Date : 01 March 2021	
		Review Due Date : 01 March 2023	

## 1.0 PURPOSE

- 1.1 This standard operating procedures(SOPs) describe the procedures for review of application for amendment of an approved clinical trial submitted to Rwanda FDA
- 1.2 Ensure the overall consistency in the norms and standards applied throughout the review of Clinical Trial Amendments
- 1.3 Ensure that the claimed amendments for an approved clinical trial are consistent with the provisions of Rwanda FDA regulations and requirements.


## 2.0 SCOPE

The SOP is applicable to the applications for amendment of an already approved clinical trial (substantial and non-substantial amendments) submitted to Rwanda FDA, additional data provided in response to deficiency or query letters for **Clinical Trial amendments**. It doesn't apply to the amendment made during the review of new application

## 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

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

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:

**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 it specifying of Clinical Trials

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

- Ensuring that this SOP is correctly and consistently implemented during the process of review of application for amendment of an approved clinical trial and related additional information
- Reviewing and providing regulatory guidance on draft feedbacks ( additional data requests, approval letters) according to the outcome of the assessment
- Monitoring and evaluation of Clinical Trial Oversight
- Ensuring that this SOP is regularly updated.

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

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

- a) Becoming fully familiar with assessment procedures for Clinical trial Applications , including trial amendments
- b) Complying with this SOP whenever carrying out assessment/ review of application for amendment of an approved clinical trial (CTAA) and related additional information
- c) Signing the declaration of interest (DOI) and Confidentiality Agreement (COA)
- d) review of the submitted Clinical Trial Applications according to the first in First out (FIFO) rules
- e) Writing assessment/review report of application for amendment of an approved clinical trial
- f) Preparing draft feedbacks ( additional data requests, approval letters) according to the outcome of the assessment
- g) Ensuring that this SOP is regularly updated.

## 6.0 DISTRIBUTION

6.1 Director General

6.2 Heads of Department of Food and Drugs Inspection and Safety Monitoring

6.3 Division Manager of Pharmacovigilance & Safety Monitoring,


6.4 Clinical Trial Analyst

6.5 Clinical Trial specialists

6.6 In charge of Quality Management System

## 7.0 REFERENCE

NA

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

## 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 N° 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 Clinical Trial Approval No DIS/FMT/050 Rev No: 0
- 9.6 Screening and Assessment templates

## 10.0 PROCEDURES

### 10.1. FIRST REVIEW/ASSESSMENT OF CLINICAL TRIAL AMENDMENTS

- 10.1.1 Access the screened Clinical Trial Application for amendment (CTAA) and Screening Report
- 10.1.2 Open a folder on your PC and give it a name corresponding to the CTAA file number, e.g. for **XX-CTAA-2021-RwandaFDA**.
- 10.1.3 Copy the Screening Report, rename and save as **R1. e.g.XX-CTAA-2021-RwandaFDA-R1**
- 10.1.4 Copy the Protocol from the CTAA and paste it at the end of the Screening Report
- 10.1.5 Perform your assessment in line with Rwanda FDA regulations and requirements in clear unambiguous language referring to deficiencies or lack of data submitted

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

10.1.6 Compare the newly submitted information in Clinical Trial amendment with the previous submitted information.

10.1.7 In the assessment report, the comments should be typed with “Times New Roman 12” fonts and 1<sup>st</sup> assessor’s (R1) comments should be introduced in **RED** font.

10.1.8 The proposed points to be communicated with the applicant shall be highlighted in **YELLOW**.

10.1.9 Ensure that all points to be communicated to the applicant (questions) are properly phrased so as to be easily understood to facilitate proper responses.

10.1.10A good communication to the applicant shall have three components:

- State the problem that you have identified;
- Identify the section of the relevant guideline that has not been complied with; and
- State what information the applicant shall submit to the Rwanda FDA

10.1.11 Save the final Clinical Trial Amendment Review Report as modified in 3, 4 and 5 above in the folder in 2 above


## 10.2 SECOND REVIEW/ASSESSMENT OF CLINICAL TRIAL AMENDMENTS

10.2.1 The second reviewer shall obtain a folder containing the first assessor’s report. N<sup>o</sup> **XX-CTAA-2021-RwandaFDA-R1**

10.2.2 Rename the first assessor’s report as **R2** e.g.: **XX-CTA-2021-RwandaFDA-R2**

10.2.3 Review the first assessor’s report and enter your comment notes as second reviewer notes in the report using 2<sup>nd</sup> assessor’s (R2) comments should be written in **BLUE**.

10.2.4 Deficiencies confirmed by the second assessor/reviewer should be **highlighted in YELLOW** or **BLUE** (in either **RED** or **BLUE** text depending) in the body of the report.


RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

- 10.2.5 The second assessor (R2) should not delete the comments and questions raised by the first assessor (R1). They may instead strikethrough the text accompanied by the second assessor's comments.
- 10.2.6 Discuss with the first assessor any areas of contention and arrive at a common position. The clinical trial analyst or Division Manager may be contacted if necessary for resolution of contentious matters and further guidance
- 10.2.7 At end the end of second Assessment report (R2), take all agreed points to be communicated with the Applicant to the appropriate section” **point to be communicated with the applicant**” CTA assessment template
- 10.2.8 List issues identified during the assessment for the follow up assessment, such as information to be confirmed, to be verified under the section ‘**General remarks to next assessors**’ of the CTAA assessment template.
- 10.2.9 List all issues identified during the CT assessment that require verification during a GCP inspection under section’ **Recommendations to GCP Inspectors**” of the CTA assessment template
- 10.2.10 Save the final Report of Clinical Trial Amendment (R2) as modified in 10.2.2

### 10.3 COMMUNICATION OF CLINICAL TRIAL AMENDMENT DEFICIENCIES

- 10.3.1 After consolidation of the deficiencies queries to be communicated to the applicant in assessment report, draft the letter to the applicant, specifying a request for any representations within 30days of receipt of the letter. Unless the applicant requested for extension
- 10.3.2 Submit the draft letter with second assessment report to the Division Manager of Pharmacovigilance and Safety Monitoring for review and further action.



RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

10.3.3 If it is a deficiency letter, dispatch the queries via email, to the local national Principal investigator with copy to sponsor and official of Rwanda FDA hierarchy

#### 10.4 ASSESSMENT OF REPONSES ON DEFICIENCIES /QUERIES

10.4.1 Access the Clinical Trial Amendment query responses and Assessment template Report

10.4.2 Rename and save the assessment template as **R1**.  
e.g. **XX-CTAA-2021-RwandaFDA-QR1**

10.4.3 Copy the question raised by previous assessors from assessment report (**R2**) and paste in the additional data assessment report template under section of **“QUESTION FROM PREVIOUS ASSESSOR”**

10.4.4 Copy or take snapshot of the proposed applicant response to the raised query responses and paste in the additional data assessment report template under section of **“REPONSE FROM APPLICANT”**


10.4.5 Perform your assessment in line with Rwanda FDA regulations and requirements in clear unambiguous language referring to deficiencies or lack of data submitted in the additional data assessment report template under section of **“COMMENT FROM ASSESSOR”**

10.4.6 In the assessment report, the comments should be typed with “Times New Roman 12” fonts and the 1<sup>st</sup> assessor’s (R1) comments should be introduced in **RED** font.

10.4.7 If the responses are unsatisfactory or partially responded to, the query may be raised again or clarifications are needed. The proposed points to be communicated with the applicant shall be highlighted in **YELLOW**.

10.4.8 Save the final additional data assessment report as above modified in section 10.4.2



RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>			Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0	
		Revision Date: : 24 February 2021	
		Effective Date : 01 March 2021	
		Review Due Date : 01 March 2023	


10.4.9 In case the applicant repeatedly provides unsatisfactorily query responses, a face to face meeting shall be convened and final decisions will be taken according to the provisions of the regulation governing clinical trial in Rwanda.

## 10.5 APPROVAL OF CLINICAL TRIAL AMENDMENTS

- 10.5.1 After completion of the Clinical trial Application review (first or second) without outstanding issues, invite the Principal investigator for face to face or virtual presentation to Rwanda FDA Team as part of approval process.
- 10.5.2 Submit the folder containing Draft Clinical Trial Amendment Approval, Second assessment report (R2), Application letter, Copy of Protocol, Approval from National Ethics Committee and evidence of Payment of non-refundable fees to Rwanda FDA 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

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>			Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0	
		Revision Date: : 24 February 2021	
		Effective Date : 01 March 2021	
		Review Due Date : 01 March 2023	


## Annexes

### TEMPLATE FOR ASSESSMENT OF CLINICAL TRIAL APPLICATIONS


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

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
	Title:		
	<b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023

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.		

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
	Title:		
	<b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023


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	<input type="checkbox"/> <b>ACCEPTED</b> <input type="checkbox"/> <b>ADDITIONAL DATA REQUESTED</b> <input type="checkbox"/> <b>REJECTED</b>
<b>Points to be communicated with the Clinical Trial Applicant:</b>  <i>Please copy all relevant information to be communicated to the CT applicant in the corresponding letter and save it accordingly</i>	
Clinical Trial Commitments (if any )	
<b>General remarks to next assessors:</b>  <i>List issues identified during the assessment for the follow up assessment, such as information to be confirmed, to be verified, etc.</i>	
<b>Recommendations to GCP Inspectors:</b>	

RWANDA FOOD AND DRUGS AUTHORITY	Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number : <b>DFC/SOP/00</b>
	Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number : 0
		Revision Date: : 24 February 2021
		Effective Date : 01 March 2021
		Review Due Date : 01 March 2023

<i>List issues identified during the CT assessment phase that require verification during a GCP inspection</i>	
--	--


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”.

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
	Title:	Revision Number : 0	
	<b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023


### CLINICAL TRIAL APPLICATION (CTA) SCREENING REPORT FORM

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


RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
		Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023
Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>			

e.	<b>Investigators' brochures</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	Comments:	
f.	<b>Capacity building plans including training and updating of staff involved in the trial</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	Comments:	
g.	<b>Clinical study reports (accomplished Clinical trial phases):</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	Comments:	
h.	<b>National Ethics Committee Clearance</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	Comments:	
i.	<b>Participant Information Leaflet (PIL).</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>




RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
 <b>RWANDA FDA</b> Rwanda Food and Drugs Authority	Title:		
	<b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023


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

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
	Title:		
	<b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>	Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023

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

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
		Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023
Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>			

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

RWANDA FOOD AND DRUGS AUTHORITY		Department/Division/ Directorate	Drugs, Food Inspections and Compliance/ Pharmacovigilance and Safety Monitoring
Document Type: <b>Standard Operating Procedure</b>		Doc. Number	: <b>DFC/SOP/00</b>
		Revision Number	: 0
		Revision Date:	: 24 February 2021
		Effective Date	: 01 March 2021
		Review Due Date	: 01 March 2023
Title: <b>REVIEW OF APPLICATION FOR AMENDMENT OF AN APPROVED CLINICAL TRIAL (CTAA)</b>			

x.	<b>List and Charter of the Data Safety Monitoring Board/Committee (DSMB).</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	Comments:	
y	<b>Declaration of Conflict of Interest, Financial Disclosure by the investigator</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	Comments:	
z	<b>Evidence of payment of prescribed fees for CTA or CTA</b>	<input type="checkbox"/> <b>Provided</b> <input type="checkbox"/> <b>Not Provided</b>
	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