

CLINICAL TRIAL APPLICATION FORM

Clinical Trial Application Form (CTA)		<input type="checkbox"/> Routine CTA	<input type="checkbox"/> Non-Routine CTA
1.	Title of the Study:		
2.	Protocol Number :		
3.	Protocol version number		
4.	Protocol date:		
5.	Clinical trial Phase		
6.	Trial objectives		
7.	Trial Design:		
8.	Investigational product's name, number or identifying mark		
9.	Indications		
10.	Comparator product (if applicable		
11.	Concomitant medications (if applicable		
12.	Number of Participants		
13.	Trial Site (s)		
14.	Duration of the trial		
15.	Amount paid for this application		
16.	Sponsor's names	Names: Institution: E-mail address: Phone number (with country code):	
17.	Principal Investigator's names	Names: Institution E-mail address: Phone number (with country code):	
18.	Contact Person names and Full address	Names: Institution E-mail address: Phone number (with country code):	
DECLARATION BY THE APPLICANT			
19.	I, (<i>Insert the names of Sponsor or PI</i>) the undersigned, hereby declare that I have submitted all required documentations, and have disclosed all information which may influence the approval of this application		

	<p>I, hereby declare that all information contained or referenced in this application is complete, accurate and is not false or misleading.</p> <p>I, agree and ensure that once the above said clinical trial is approved, will be conducted according to the submitted protocol, legal, ethical and regulatory requirements of Rwanda FDA</p>		
20.	Names of applicant	Signature	Date