*(This application should be completed and signed by sponsor or Principal investigator)*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Clinical Trial Application Form (CTA)** | | | | |
|  | Title of the Study: | |  | |
|  | Protocol Number : | |  | |
|  | Protocol version number | |  | |
|  | Protocol date: | |  | |
|  | Clinical trial Phase | |  | |
|  | Trial objectives | |  | |
|  | Trial Design: | |  | |
|  | Investigational product’s name, number or identifying mark | |  | |
|  | Indications | |  | |
|  | Comparator product (if applicable | |  | |
|  | Concomitant medications (if applicable | |  | |
|  | Number of Participants | |  | |
|  | Trial Site (s) | |  | |
|  | Duration of the trial | |  | |
|  | Amount paid for this application | |  | |
|  | Sponsor’s names | | Names:  Institution  E-mail address:  Phone number (with country code): | |
|  | Principal Investigator’s names | | Names:  Institution  E-mail address:  Phone number (with country code): | |
|  | Contact Person names and Full address | | Names:  Institution  E-mail address:  Phone number (with country code): | |
| **DECLARATION BY THE APPLICANT** | | | | |
|  | I, (*Insert the names of Sponsor or PI*) the undersigned, hereby declare that I have submitted all required documentations, and have disclosed all information which may influence the approval of this application  I, hereby declare that all information contained or referenced in this application is complete, accurate and is not false or misleading.  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. | | | |
|  | **Names of applicant** | **Signature** | | **Date** |
|  |  | |  |