



Kigali on 3 / 02 / 2023

Ref. N°: FDISM/PVSM/500 /FDA/2023

Stakeholders in Clinical Trials (All)

Re: Circular on Public consultation and call for comments on regulatory documents

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA), especially in its article 8 paragraphs 7, 12, and 16, the Authority is mandated to regulate and inspect clinical trials. Rwanda FDA has reviewed and updated various regulatory documents related to clinical trials oversight in order to achieve its mission while adhering to international quality standards for designing, conducting, recording, and reporting in clinical trials.

Rwanda FDA would like to inform clinical trials stakeholders and the general public that the draft of updated regulatory documents listed below is being circulated for public consultation and comments starting from February 1st, 2023.

1. V02-Regulation CBD/TRG/015 governing the conduct and Inspection of Clinical Trials in Rwanda;
2. V01-Guidelines DIS/GDL/044 on Good Clinical Practices (GCP) in Rwanda;
3. V02-Guidelines DIS/GDL/033 on clinical trial applications in Rwanda;
4. V01-Guidelines DIS/GDL/042 on review and approval of Clinical Trial Applications;
5. V01-Guidelines DIS/GDL/043 on GCP inspections of Clinical Trials in Rwanda;
6. V00-Guidelines on Handling Safety Data in Clinical Trials.

The aforementioned documents with the comment form No ODG/QMS/FMT/023 have been uploaded to the Rwanda FDA website www.rwandafda.gov.rw under stakeholders and will be available for comments for 30 calendar days. Thereafter, there will be a stakeholder meeting to validate the inputs/comments.

The Authority would like to invite individuals, sponsors, principal investigators, Contract Research Organizations, Ethics Committees, and other interested parties to provide written input/comments using the comment form No ODG/QMS/FMT/023 and send the completed form to the email: info@rwandafda.gov.rw not later than 03/03/2023.

Sincerely,



Dr. Emile BIENVENU
Director General