MINISTRY OF HEALTH **REPUBLIC OF MALI**

AND PUBLIC HYGIENE **One People-One Goal – One Faith**

GENERAL SECRETARIAT

DIRECTORATE FOR PHARMACY AND MEDICINE

DOCUMENTS TO BE PROVIDED FOR A CLINICAL TRIAL:

1. The application for authorization to conduct a clinical trial addressed to the Minister of Health and Public Hygiene;
2. A copy of the Ethics Committee's approval;
3. A copy of the protocol of the clinical trial signed by the promoter (s);
4. A copy of the document of clear consent;
5. A copy of the Investigator's hand out in French;
6. A copy of the Insurance Contract covering the entire period of the Clinical Trial;
7. A commitment signed by the sponsor or promoter;
8. A copy of the CVs of all investigators;
9. A copy of the products good manufacturing certificate;
10. A copy of the product stability certificate;
11. A copy of the certificate (s) of analysis
12. A copy of the country's Marketing Authorization of the home country.