TANZANIA FOOD AND DRUGS AUTHORITY

NOTICE TO ALL CLINICAL TRIAL INVESTIGATORS AND SPONSORS

1. Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act, Cap 219 to control quality, safety and effectiveness of food, medicines, cosmetics, medical devices and diagnostics. Among other functions, TFDA is also responsible for regulating clinical trials.

2. The TFDA would like to notify trial investigators and sponsors that it has reviewed the Guidelines for Application to Conduct Clinical Trials in Tanzania.

3. The Guidelines highlights amongst others, new application requirements to include the introduction of a Common Technical Document (CTD) format to be filled out during submission of applications.

4. In addition, new Guidelines for Conducting Good Clinical Practice (GCP) and Good Clinical Laboratory Practices (GCLP) Inspection first edition, June 2017 has been crafted and is also ready for use.

5. All future applications and guidance on inspection activities will be based on these guidelines.

6. All trial investigators and sponsors are now required to access these documents at TFDA HQ offices or through our website (www.tfda.go.tz).

7. For further information please contact the Authority through the following address;

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