NAFDAC CLINICAL TRIAL ADVISORY COMMMITTEE (NCTAC) TERMS OF REFERENCE

1. Introduction

The Clinical Trials Advisory Committee (CTAC) is an independent external advisory body, established in June 2019, to provide NAFDAC with medical and scientific advice on issues related to clinical trials. The CTAC offers expert recommendations to assist the Agency in making appropriate regulatory decisions, however, the decision-making responsibility remains with NAFDAC.

The Clinical Trial Advisory Committee operates in accordance with the Food, Drugs and Related Products (Registration, etc.) Act Cap No. F33 LFN, 2004 that empowers NAFDAC to authorize and monitor clinical trials in Nigeria.

2. Purpose

The purpose of the Terms of Reference is to define the responsibilities, composition, and standard of conduct of the Clinical Trial Advisory Committee (CTAC) of the National Agency for Food and Drug Administration and Control (NAFDAC).

3. Responsibilities

3.1 The primary focus of the committee's deliberations should be the protection of the human subjects, volunteers or patients, quality, safety and efficacy of the product under study.

3.2 The committee should assess the available information for scientific merit or demerits.

3.3 The committee should submit recommendations to the DG (NAFDAC).

4. Membership

4.1 The CTAC is composed of multidisciplinary members, independent in its reflection, advice and decision. It is constituted and operates under the authority of the Director-General (DG) of NAFDAC.

4.2 The DG (NAFDAC) appoints not less than six (6) members of the committee with expertise in clinical research.

4.3 The Chairperson of the CTAC is appointed by the DG (NAFDAC).

4.4 The appointment shall be for a period of two (2) years which is renewable

4.5 Consulting (ad hoc) members with specific expertise may be invited by the CTAC chair, when necessary. These (ad hoc) members have equal voting rights pertaining to the particular study.

4.6 A member may resign or be requested to do so by the DG (NAFDAC) for good cause on the written recommendation of the Chairperson.

4.7 When a member resigns, the DG (NAFDAC) should fill the vacancy by appointing a person for the unexpired portion of the term of office of the Committee.

4.8 A member who fails to observe committee meeting attendance requirements, who fails to carry out duties and allocated tasks as required by the Chairperson, or who

discloses a significant conflict of interest that cannot be managed appropriately may be requested to resign from the committee.

5. Meetings

5.1 The Clinical Trials Advisory Committee meets at least annually, and may meet as often as required, to review and provide recommendations regarding clinical trial.

5.2 A quorum consists of a simple majority (fifty per cent plus one).

5.3 Decisions should be reached by consensus if possible. When a vote is required, a simple majority serves, with the Chairperson having a casting vote in addition to his/her deliberative vote, should the vote be tied.

5.4 Records of meetings must be made available to DG (NAFDAC).

6. Standard of Conduct Expected of members

6.1 In carrying out their duties, members of committee must:

6.1.1 Uphold ethical standards by acting to foster public confidence in the CTAC's ability to act in the public interest and for long term public good.

6.1.2 Demonstrate integrity, honesty, good judgment and professionalism.

6.1.3 Make decisions in the interest of CTAC, with a view to the public interest, and with regard to the merits of each case.

6.1.4 Disclose fully any private or professional conflict of interests that could affect CTAC actions or that could present a potential conflict of interest and put ethical practice at risk.

7. Conflict of Interest

7.1 A conflict of interest occurs when an individual has an interest that competes with the interests of the CTAC. The competing interest may be real, potential or perceived, direct or indirect.

7.2 All activities that involve research, commercial or financial interests, whether real, potential or perceived, which may conflict with an interest of the CTAC or with the duties of an individual member, must be disclosed promptly to NAFDAC.

8. Remuneration

8.1 Committee members shall be compensated for their time and expertise through moderate remuneration of their transport, accommodation and sitting allowance (honorarium), paid per sitting.

9. Misconduct

9.1 The following shall constitute a misconduct

9.1.1 Misleading the CTAC or misrepresenting the CTAC

9.1.2 Abuse of privileged information

9.1.3 Fabrication or falsification of reports

9.1.4 Failure to disclose a material conflict of interest

9.1.5 Divulging confidential information to a third party without permission

9.1.6 A failure to attend a minimum of two consecutive CTAC meetings.