

FDA ADVISORY
No: **2023-1925**

08 SEP 2023

TO: ALL PROFESSIONAL HEALTH SOCIETIES, CHIEFS OF HOSPITALS AND MEDICAL CENTERS, HEALTHCARE PROFESSIONALS AND ACADEMICIANS

SUBJECT: Call for Nomination as member of the Clinical Trial Scientific Advisory Committee (SAC)

Pursuant to Republic Act No. 9711, otherwise known as the “Food and Drug Administration (FDA) Act of 2009”, the FDA shall have the function to supervise, monitor and audit research studies on health and safety issues of health products undertaken by entities duly approved by the FDA. This includes all phases of clinical trials on investigational products for eventual product registration and marketing, or studies which will generate more information on the safety and efficacy of registered drug products.

As per Administrative Order No. 2020-0010 entitled “Regulations on the Conduct of Clinical Trials for Investigational Products”, a duly constituted Scientific Advisory Committee (SAC) composed of subject matter experts (SMEs) may be consulted by the FDA or Regulatory Reviewers to provide expert recommendations in the review of clinical trial applications. This is to ensure the ensure the full protection of the rights and safety of human participants and the integrity of the clinical trial data following the principles of the Good Clinical Practice and related FDA regulations.

In line with the above, the FDA is starting the call for nomination for experts in the following fields:

1. Pharmacology
2. Drug Research and Development (R&D)
3. Clinical Medicine/Medical Specialist
4. Clinical Epidemiology
5. Clinical Research and Biostatistics
6. Toxicology
7. Biotechnology/Medical Laboratory Science
8. Research Ethics

The following are the required qualifications of the SAC members:

- Recognized specialist in their respective filed of expertise;
- With at least 5 years of experience in their respective field;
- Willingness to disclose conflicts of interest



The nominees will be evaluated according to their educational attainment and field of expertise, relevance of work experience, relevance of training experiences within the last ten (10) years, publications and conflicts of interest.

We hope to receive the names and contact details of the nominees on or before **29 September 2023** and we shall reach out on the requirements and how to proceed with the application.

Kindly submit the list of the nominees at clinicalresearch@fda.gov.ph. If you have any questions or concerns, please do not hesitate to contact us through the same email address or you may call Telephone No. (02) 8809-5596.

Thank you very much.



DR. SAMUEL A. ZACATE
Director General