EXTERNAL ADVERT

The National Drug Authority (NDA) is an autonomous body which was established by the National Drug Policy and Authority Act Cap 206, Laws of Uganda (2000 Edition) to regulate Human and Veterinary Medicines and other healthcare products. NDA's mandate is to ensure quality, safety and efficacy of human and veterinary medicines and other healthcare products through the regulation and control of their production, importation, distribution and use.

NDA received a three-year grant titled *"Consortium for Developing Regulatory Capacity for Clinical Trials Using Gene Therapy Products and Strengthening Pharmacovigilance in The Conduct of Clinical Trials in Uganda" (CAPACITY 2023)*, which will run up to 2027. The CAPACITY 2023 grant (reference: 101145599) is a project that was awarded under the Global Health European and Developing Countries Clinical Trials Partnership (EDCTP3) Joint Undertaking and by European Union through the Horizon Europe Program (HORIZON-JU-GH-EDCTP3-2023-01-05).

Therefore, the Authority is looking for competent people with required skills, attitude and qualifications to fill the position of **Regulatory Officer – Safety** to support the CAPACITY 2023 Project.

The external advertisement runs from 11th to 22nd April at 5:00 PM.

Please take note of the eligibility requirements before submission:

1. POST TITLE: REGULATORY OFFICER -SAFETY

Vacancies	:	**One (1)**
Salary Scale	:	NDA F1
Directorate	:	Product Safety- CAPACITY 2023 Grant
Reports to	:	Manager Clinical Trials
Direct Reports	:	N/A
Duration	:	2 Years (May 2025 - April 2027)
Location	:	Head Office

2.0 MAIN PURPOSE OF JOB

Perform clinical trials' oversight functions related to improving safety management at the National Drug Authority.

3.0 DUTIES AND RESPONSIBILITIES

3.1 Review clinical trial applications and submissions. To achieve this, the job holder will:

(a) Carry out qualitative scientific assessment of the applications, coming up with an evaluation report and communicating all the findings to the principal investigators.

(b) Review safety information arising out of the studies and providing responses to such information

3.2 Review of Serious Adverse Events and compilation of safety summary reports for trend analyses.

3.3 Inspection of clinical trial sites for compliance to the conditions of the clinical trial certificate and participate in writing GCP inspection and trip reports

3.4 Participate in the development of professional guidelines, manuals, standard operating procedures and internal documents related to clinical trial oversight

3.5 Participate in training/workshops, seminars and retreats as required or requested, for capacity building. These may be intra- or inter-directorate, regional or international.

3.6 Attend internal or external technical meetings as required or requested

3.7 Undertake any other responsibilities, tasks or activities as reasonably required as the above is given as a broad range of duties and is not intended to be complete description of all tasks.

4.0 QUALIFICATION

- Bachelor's degree in Medicine and Bachelor of Surgery (MBChB,) from an accredited institution.

Minimum Experience:

- A minimum of 2 years of post-graduation experience and active involvement in a clinical setting
- Familiarity with Good Clinical Practice (GCP) guidelines and other relevant regulatory standards
- Ability to critically evaluate clinical data and provide insightful contributions related to patient safety monitoring
- Strong verbal and written communication skills, with the ability to effectively collaborate with multidisciplinary teams. Experience in mentoring or supervising junior medical staff is an advantage.

5.0 FUNDING

This position is supported by CAPACITY 2023 project (Reference: 101145599) granted by the European Union through Horizon Europe HORIZON-JU-GH-EDCTP3-2023-01-05.

Application Procedure

Please submit a cover letter, copies of your academic qualifications together with your Curriculum Vitae (CV) not later than **5:00pm on Tuesday 22nd April 2025.**

PLEASE DELIVER YOUR APPLICATIONS TO THE REGISTRY.

Your application should be addressed to the Director Human Resources and Administration, National Drug Authority, NDA Tower, Plot 93 Buganda Road

Global Health EDCTP3

"The project is funded by the Global Health EDCTP3 and The European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or the EDCTP3. Neither the European Union nor the granting authority can be held responsible for them."