

REQUEST FOR EXPRESSIONS OF INTEREST (REOI) FOR INDIVIDUAL CONSULTANTS

CONSULTANCY SERVICES FOR REVIEW OF THE NATIONAL HEALTH, BIOSAFETY AND ENVIRONMENTAL REGULATORY FRAME WORK, LEGISLATION, REGULATIONS, INFRASTRUCTURE AND CAPACITY FOR THE RESEARCH DEVELOPMENT AND DEPLOYMENT OF GENE DRIVE MOSQUITOES IN BURKINA FASO

PROCUREMENT NUMBER: 91/AUDA/OSTI/IVM/ICS/2023

Method: Individual Consultants Selection (ICS) - Individuals Only

1. INTRODUCTION

Reference is made to the African Union Executive Council Decision that took note of the progress made by the African Union High Level Panel on Emerging Technologies (APET) regarding the inception and analysis of Gene Drive for control and elimination of malaria, and further, requesting AU Member States to harness emerging technologies such as gene drives for socio-economic development (EX.CL/Dec.987(XXXII)Rev1).

Based on the adopted recommendations of APET, the AUDA-NEPAD piloted an Integrated Vector Management (IVM) platform using malaria as a pathfinder disease and gene drive as the pathfinder technology in West Africa in August, 2018

As an outcome, the West African Integrated Vector Management Platform was established with Burkina Faso serving as lead country in the regulation, research and development of Gene drive technology and the gene drive modified mosquito. Burkina Faso has established a National IVM platform to support the collaborative and collective effort required for GDDM regulation, research and development and the country has made tremendous progress and are currently in STAGE 2 of product development and about to enter stage 3.

2. OBJECTIVES OF THE ASSIGNMENT

- I. To review the existing Health including ethics legislation, regulations and guidelines as it relates to the conduct of clinical trails for gene drive mosquito technology and conduct a capacity needs assessment for the regulatory assessment of clinical trial dossiers and clinical trial monitoring/inspection and implementation of Good clinical Practice (GCP)
- II. To review existing Environmental and Biosafety legislations, regulations and guidelines as it relates to GENE DRIVE technology and its implementation and use, conduct a capacity needs assessment of regulatory capacity to conduct assessment of dossiers relating to Gene drive applications and monitoring of research progress, Risk Assessment and compliance inspection
- III. To develop a road map for the implementation of findings and/or recommendations of the consultants work.

SCOPE/MAIN RESPONSIBILITIES OF THE ASSIGNMENT:

- I. Desk review of National Documents (Policies, Legislation, Regulations, Guidelines)
- II. Site visits to regulatory Authorities and Research Facilities.

- III. Conduct Stakeholder engagement on gene drive technology to evaluate knowledge, perceptions and views of policy makers, regulators, Health/Biosafety/Environmental Professionals/ implementing agencies, researchers, civil society, and the community
- IV. Conduct stakeholder meetings to disseminate findings and recommendations of the consultancy and adoption of implementation road map.

3. DELIVERABLES

3.1. A Consultancy report with the following content

- a. Inventory of laws, decrees, policy guidelines and regulatory requirements for biosafety, environmental assessment, research and product development in GBVC and clinical trials
- b. Analysis of knowledge, perceptions and attitudes in both health and biosafety sectors with regards to biosafety, environmental assessment, research and product development in GBVC and clinical trials
- c. Identification of points of weakness and gaps on documentation required to guide health research and regulation and clinical trials for GBVC
- d. Identification of gaps on technical and scientific capacity strengthening for research and regulation in biosafety, environmental assessment and different phases of product development from biotechnology
- e. Modalities for strengthening institutional collaboration and partnership for GBVC in Burkina Faso
- f. An implementation road map for research, regulation and implementation of GBVC in Burkina Faso.

3.2. Report of a convened workshop for regulatory experts and key stakeholders to share the outcomes of policy and regulations review, available capacity and infrastructure (research ethics, biosafety, health regulation, environmental assessment) assessments with the following outcomes:

- a. Findings from expert consultation and implementation road map is shared with regulators and key stakeholders for GBVC in Burkina Faso
- b. Collaborative relationships are strengthened among national key stakeholders (parliament, research, ethics, biosafety, health regulation, environmental assessment, civil society and community stakeholders) for GBVC.
- c. Regulatory process and dossier/application review process (ethics, health, biosafety, environmental assessment) is mutually shared and discussed
- d. Similarities and differences in process/application/guidelines are identified and discussed.
- e. Gaps are identified and addressed, including decisions to enhance synergies between institutions, and to avoid unnecessary overlaps
- f. Recommendations from the consultancy and implementation road map adopted

4. AUDA-NEPAD now invites eligible individual consultants (“Consultants”) to indicate their interest in providing the Services. Interested Consultants should provide information demonstrating that they have the required qualifications and relevant experience to perform the Services.

5. QUALIFICATIONS, EXPERIENCE AND COMPETENCIES

Qualifications and Skills

- A minimum of a master’s degree in natural sciences, genetics, biosafety and environmental regulation, vector management, public health or a related discipline; a PhD in Natural Sciences is an added advantage

Experience

- At least ten (10) years of relevant work experience in genetically modified mosquitoes or a related field.
- Experience in providing consultancy services for randomized clinical trials.

- Experience in protocol writing, reviewing, IRB, and regulatory submission, and clinical monitoring
- Experience as a Principal Investigator and Co-Investigator in various research projects related to malaria, COVID-19, dengue, and other infectious diseases.
- Experience in conducting clinical trials, observational studies, and epidemiological studies
- Excellent knowledge and competency in health or biosafety research and regulation, especially in the genetically modified mosquitoes ecosystem

6. SHORTLISTING CRITERIA

For evaluation of the expressions of interest, the following criteria will be applied:

- i) Qualifications, Relevant Training and General Education (30 points);
- ii) Experience in the Specific Assignment as Described in the TORs (60 points); and
- iii) Knowledge of the Region & Local Conditions (10 points).

A Consultant will be selected in accordance with Individual Consultant Selection (ICS) method set out in the AU Procurement Manual.

7. SUBMISSION REQUIREMENTS

Interested candidates are requested to submit the following documents for AUDA-NEPAD consideration:

- I. Cover letter confirming compliance to eligibility;
- II. Signed declaration of undertaking (Attached as an annex below);and
- III. Curriculum Vitae (CV).
- IV. Proof of stated qualifications in the form of the copies of the degrees obtained

8. REPORTING AND TIME SCHEDULES:

- I. In undertaking this exercise, the consultant will be expected to frequently exchange and interact with the Senior Advisor: Office of Science, Technology and Innovation of AUDA-NEPAD.

9. Only Individual Consultants are eligible for this assignment if they fulfil the following eligibility criteria:

- a) Have no conflict of interest in relationship to performance of this assignment;
- b) Are not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the African Union Commission, World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank. Further, are not ineligible pursuant to a decision of the United Nations Security Council;
- c) Have not been convicted by a final judgement or a final administrative decision or subject to financial sanctions by the United Nations or Country for involvement in a criminal organisation, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons which themselves are subject to such convictions or sanctions;
- d) Are not being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganisation or being in any analogous situation;
- e) Are not involved in corruption: offering, giving, receiving or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party;
- f) They have not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization or any other illegal activity detrimental to the AUDA-NEPAD financial interests;
- g) they have not been declared guilty of gross professional misconduct proven by any means which AUDA-NEPAD can justify;
- h) Comply with their national tax and social security laws

Interested consultants may obtain further information from the address listed below. All Expression of Interests should be sent electronically to email listed below.

10. Expressions of interest must be delivered to the address below by email on or before **September 19th, 2023 14:30 hours (South African Time)**. All EOI's must be marked **"91/AUDA/OSTI/IVM/ICS/2023– CONSULTANCY SERVICES FOR REVIEW OF THE NATIONAL HEALTH, BIOSAFETY AND ENVIRONMENTAL REGULATORY FRAME WORK, LEGISLATION, REGULATIONS, INFRASTRUCTURE AND CAPACITY FOR THE RESEARCH DEVELOPMENT AND DEPLOYMENT OF GENE DRIVE MOSQUITOES IN BURKINA FASO"** in the subject line of the email.
11. **Privacy Policy:** *AUDA-NEPAD Procurement office collects and uses your personal information for "Procurement Process" when you intend to compete and deliver any service or goods for the organization either individually or as a firm based on your consent. Your personal data is our highest security and kept for a period strictly necessary for the purpose set out. This privacy notice supplements the AUDA-NEPAD standard privacy notice and should be read in conjunction with the same available on AUDA-NEPAD website.*

The Chairperson Internal Procurement Committee (IPC)

AUDA-NEPAD

230, 15th Road, P. O. Box 218 Midrand,
1685 Johannesburg, South Africa

Email: procurement@nepad.org & copy ngonik@nepad.org

Attention of: Head of Procurement Division

DECLARATION OF UNDERTAKING

{Location, Date}

To: **The Chairperson Internal Procurement Committee (IPC)**

AUDA-NEPAD

230, 15th Road, P. O. Box 218 Midrand,

1685 Johannesburg, South Africa

Attention of: Head of Procurement Division

1. I, the undersigned, offer to provide the services for {insert Title and Procurement Number} in accordance with your Request for Expression of interest dated {insert Date}
2. I declare that I:
 - i) Have no conflict of interest in relationship to performance of this assignment;
 - j) Am not subject to, and not controlled by any entity or individual that is subject to, a temporary suspension or a debarment imposed by the African Union, World Bank or any other multilateral development bank and being listed on the website <http://www.worldbank.org/debarr> or respectively on the relevant list of any other multilateral development bank. Further, are not ineligible pursuant to a decision of the United Nations Security Council;
 - k) Have not been convicted by a final judgement or a final administrative decision or subject to financial sanctions by the African Union, United Nations or Country for involvement in a criminal organisation, money laundering, terrorist-related offences, child labour or trafficking in human beings; this criterion of exclusion is also applicable to legal Persons, whose majority of shares are held or factually controlled by natural or legal Persons which themselves are subject to such convictions or sanctions;
 - l) Am not being bankrupt, wound up or ceasing our activities, having our activities administered by courts, having entered receivership, reorganisation or being in any analogous situation;
 - m) Have not been the subject of a judgment which has the force of res judicata for fraud, corruption, involvement in a criminal organization or any other illegal activity detrimental to the AUDA-NEPAD financial interests;
 - n) Have not been declared guilty of gross professional misconduct proven by any means which AUDA-NEPAD can justify;
 - o) Are not involved in corruption: offering, giving, receiving or soliciting, directly or indirectly, anything of value to influence improperly the actions of another party;
 - p) Comply with their national tax and social security laws.
3. I, the undersigned, certify that to the best of my knowledge and belief, that my CV correctly describes myself, my qualifications, and my experience. I understand that any willful misstatement described herein may lead to my disqualification or dismissal, if engaged;
4. I hereby declare that at any point in time, at AUDA-NEPAD's request, I will provide certified copies of all documents to prove that I have the qualifications and the professional experience which are attached to this CV as photocopies;
5. By signing this statement, I also authorize the AUDA-NEPAD's to contact my previous or current employers indicated in my CV, to obtain directly reference about my professional conduct and achievements.

We remain,

Yours sincerely,

Signature:
Name of Consultant:
Address