TERMS OF REFERENCE FOR CONSULTANCY	
Title of the Consultancy:	Review of the National Health, Biosafety and Environmental Regulatory framework, legislation, regulations, infrastructure and capacity for the research development and deployment of Gene Drive mosquitoes in Burkina Faso
Consultancy type: *(individual or firm)*	Individual
Directorate & Division	Office of Science Technology and Innovation-IVM Project
Contact Person:	Prof Aggrey Ambali
Procurement Number (from procurement plan)	91/AUDA/OSTI/IVM/ICS/2023

Background

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

Rationale

In order for Burkina Faso to move to stage 3 of product development there is an urgent need to review the existing regulatory and research land scape in the country in order to identify any gaps and address possible needs to ensure a safe ,effective and efficient development process and regulatory environment that will gauranty the release of a safe and effective product in a timely fashon.

The objectives of the assignment

GENERAL OBJECTIVES

1 To Document and review the National regulatory frame work in Burkina Faso for Gene Drive

Technology

2 To review the existing National Health, biosafety and environmental regulatory legislation, regulations, guidelines, infrastructure and capacity in Burkina Faso as it applies to Gene Drive Technology and the research and development of the GDDM and its deployment.

Specific objectives

1. 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)
2. 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
3. To develop a road map for the implementation of findings and/or recommendations of the consultants work.

Scope of work, activities and Tasks

1 Desk review of National Documents (Policies, Legislation, Regulations, Guidelines)

2 Site visits to regulatory Authorities and Research Facilities.

3 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

4.Conduct stakeholder meetings to disseminate findings and recommendations of the consultancy and adoption of implementation road map.

Capacity Building Program

n/a

Expected results and deliverables

Deliverables:

1) A Consultancy report with the following content

- Inventory of laws, decrees, policy guidelines and regulatory requirements for biosafety, environmental assessment, research and product development in GBVC and clinical trials
- 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
- Identification of points of weakness and gaps on documentation required to guide health research and regulation and clinical trials for GBVC

- 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

- Modalities for strengthening institutional collaboration and partnership for GBVC in Burkina Faso

- An implementation road map for research, regulation and implementation of GBVC in Burkina Faso.

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:

- Findings from expert consultation and implementation road map is shared with regulators and key stakeholders for GBVC in Burkina Faso

- Collaborative relationships are strengthened among national key stakeholders (parliament, research, ethics, biosafety, health regulation, environmental assessment, civil society and community stakeholders) for GBVC.

- Regulatory process and dossier/application review process (ethics, health, biosafety, environmental assessment) is mutually shared and discussed

- Similarities and differences in process/application/guidelines are identified and discussed.

- Gaps are identified and addressed, including decisions to enhance synergies between institutions, and to avoid unnecessary overlaps

- Recommendations from the consultacy and implementation road map adopted

Location

Ouagadougou / Bobo Dilasso

Timeframe of the assignment

60 consultancy days

Deliverables/Reports/Milestones Schedule

Milestone	Estimated Duration	Delivery Period
Inception Report	5 consultancy days	2nd Week after start of consultancy
Submission of Draft Report	20 consultancy days (4 weeks cumulative)	6 weeks after inception report consultancy
Submission of Revised Report	15 consultancy days (8 weeks cumulative)	8 weeks after draft report
Validation workshop	10 consultancy days (10 weeks cumulative)	10 weeks after revised report

Submission of Final Report	10 consultancy days (12 weeks cumulative)	12 weeks after validation workshop

Submission & approval of reports

Three Hard copies and an electronic copy Submitted to Project Manager of IVM and approval by Head OSTI Prof Aggrey Ambali.

Language requirements

French and English

Person Days/Months

60 consultancy days

Governance, support and facilities to be provided by AUDA-NEPAD

1) Review of Inception, Draft and Final Reports
2) Funds for Stakeholder Validation Workshop in Burkina Faso
3) Professional Fees only for consultant

Proposed Payment Schedule

1st Payment: ***Thirty (30) percent*** of the lump-sum amount shall be paid upon submission and approval of draft 1 report;
2nd Payment: ***Thirty (30) percent*** of the lump-sum amount shall be paid upon submission and approval of draft 2 report
Final Payment: ***Forty (40) percent*** of the lump-sum amount shall be paid upon submission and acceptance of final report

Experience of the Firm

N/a

Qualification and work experience required for Key Experts

Given the focus of the consultancy in Burkina Faso, Key Experts should possess strong expertise in relevant fields, such as genetics, biosafety, environmental regulation, vector management, and public health in Burkina Faso. Additionally, experience in conducting and evaluating clinical trials, as well as knowledge of relevant international regulations and best practices in clinical research and genetic technologies in Burkina Faso, would be highly valuable for the Key Experts in this consultancy

The consultancy requires Key Experts with the following qualifications and work experience:

1. Education: 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 desired.

2. Professional Experience: At least ten (10) years of relevant work experience in genetically modified mosquitoes or a related field.

3. Research Experience:
   - 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.

4. Consultancy Experience:
   - Experience in providing consultancy services for randomized clinical trials.
   - Experience in protocol writing, reviewing, IRB, and regulatory submission, and clinical monitoring.

5. Skills: Key Experts should possess the following skills:
   - Above-average knowledge of the Burkina Faso Science, Technology, and Innovation landscape.
   - Excellent knowledge and competency in health or biosafety research and regulation, especially in the genetically modified mosquitoes ecosystem.
   - Technical competence in drafting reports, scientific writing, and editing skills.
   - Solid knowledge of concept development, research, analysis, and reporting on results.
   - Excellent development-oriented writing and science editing skills.
   - Excellent planning, creativity, and organization skills.
   - Excellent oral and interpersonal skills, with the ability to work as part of a team.
   - Willingness to learn and respond positively to feedback.
   - Excellent working knowledge of computer applications such as MS Word, Excel, PowerPoint, etc.
   - Good research data management and highly developed IT skills, with the ability to present information clearly.