Terms of Reference to recruiting a Consultant for the EDCTP "ECOWAS-RegECs" project:

"Practical strengthening of regulatory and ethics oversight on clinical trials in West Africa using Lassa Fever vaccine development projects and increase regulatory maturity level in targeted countries"

Background

The project shall enhance clinical trial oversight capacity of Ethics Committees (ECs) and National Regulatory Authorities (NRAs) in West Africa, enhance preparedness for licensure of Lassa Fever vaccines or a possible emergency use approval in case of an outbreak (Work Package 2), and enhance the Maturity Level of selected NRAs (Work Package 3).

Lassa fever is a zoonotic disease associated with acute and potentially fatal hemorrhagic illness caused by Lassa virus (LASV). The disease has been shown to be prevalent in many West African countries, such as Benin, Ghana, Guinea, Liberia, Mali, Nigeria, and Sierra Leone. In these countries, both sporadic cases and prolonged outbreaks of the disease are observed. Neighboring countries are also at risk because the animal vector lives throughout the region. The overall case-fatality rate of Lassa Fever is 1%. The number of Lassa virus infections per year in West Africa is estimated at 100,000 to 300,000, with approximately 5,000 deaths. The condition keeps increasing by the day and the need to find solutions to address the situation to reduce the death incidence is very relevant. The urgency initiated the **ECOWAS-RegECs project,** to enable both the National Regulatory Authorities and Ethic Committees strengthen their capacities and competences to a maturity level to fast-track the availability of effective tests, vaccines and medicines that can be used to save lives and avert large scale crises.

The European and Developing Countries Clinical Trials Partnership **(**EDCTP/ "ECOWAS-RegECs") project arose from the **Coalition for Epidemic Preparedness Innovations** (**CEPI**) intend to offer preparedness strategy for Africa through practical regulatory agencies (RA)

strengthening using the Lassa fever vaccine development portfolio. In May 2022 EDCTP3 published a CfP under Framework Programme 2023 for 'strengthening ethics and regulatory capacity in sub-Saharan Africa, which perfectly fit with CEPI's preparedness strategy by use of Lassa portfolio for practical strengthening.

As coordinating organization, CEPI has formed a consortium with Ghana FDA and WAHO to execute the strengthening program "ECOWAS-RegECs" funded by EDCTP.

The consortium is working in partnership with vaccine developers, ECOWAS, AMRH, AVAREF, WHO/CIP, PEI and BMGF and ECOWAS member states as stakeholders on the practical strengthening by simulations of previous LASSA fever vaccine related scientific advice procedures and clinical trial applications, and by including observer counties in future live applications through the established common review procedures of the AVAREF platform (Work Package 2).

In Work Package 3, Ghana FDA and WAHO will work together for maturity level enhancement of selected ECOWAS countries. This Work Package is an important complementary general strengthening activity to ensure regional preparedness for clinical trial oversight and vaccine licensure in the region, which will be needed also beyond for LASSA fever vaccines. The establishment of a regional plan and selection activity is planned to be supported by a consultant under the oversight by WAHO.

The "ECOWAS-RegECs" project is important for LASSA preparedness in West Africa and intends to strengthen the regulatory and ethics capabilities and capacity in the ECOWAS region.

Purpose for the recruitment of the Consultant

Consultant is being recruited to search / map and provide the process to identify National Regulatory Authorities (NRAs) in the ECOWAS region whose regulatory capacity should be strengthened and enhanced to achieve WHO maturity level 3 (ML3) for vaccines' Clinical Trials and Marketing Authorization under consideration of LASSA related preparedness needs. He or she would also provide input to an improvement plan that would be followed by the selected country agencies for enhancement from ML2 to 3 or from ML3 to 4 status.

Objectives:

1. Obtain/map benchmarking outcome of the overarching Regulatory System and Clinical Trials functions of all ECOWAS countries against the WHO GBT published indicators in the areas of vaccine regulation.
2. Establish and validate criteria for selection of most eligible candidates for Maturity Level enhancement efforts under this project.
3. Agree on selected candidates for Maturity Level enhancement efforts under this project with the stakeholder community.

Expected Outcomes:

1. Regulatory System and Clinical Trials functions of NMRAs in ECOWAS countries mapped, based on WHO GBT indicators in the areas of vaccine regulation.
2. Criteria for selection of most eligible candidates for Maturity Level enhancement efforts under this project established and validated.
3. Selected candidates for Maturity Level enhancement efforts under this project agreed with the stakeholder community.
4. A regional plan and selected planned activities established with support by the consultant under WAHO oversight.

Contractor:	GFDA
Responsibility:	WAHO in consultation with key stakeholders.
Deliverables:	All reports, findings and recommendations should be submitted to WAHO, GFDA and CEPI and will be shared with AMRH.
Cost:	Consultant for maximum 3 to 4 months