

PROGRESS OF IGORCADIA PROJECT

Main results achieved during the first year (December 1st 2017 – November 30th 2018) **Perspectives and Expected Impact**

The project 'Improved Governance and Research Capacities in Diagnostics for Infectious Diseases of the Liberian Medicines and Health Products Regulatory Authority – LMHRA- (IGORCADIA) aims at building capacities of the LMHR to developed its capacity to regulate the use of diagnostics in research and the research on diagnostics and implementing these regulations in promoting a rational use of diagnostics. Also, the principal beneficiary of the project, will be training on good clinical practice, good laboratory practice, fundamentals of medical ethics and diagnostics research.

The project started in December 2017 and is led by the Barcelona Institute of Global Health (ISGlobal) in collaboration with the NGO Juan Ciudad Foundation (FJC), the Liberian Medicines and Health Products Regulatory Authority (LMHRA) and the Saint Joseph's Catholic Hospital (SJCH), in Monrovia, where all activities take place.

The specific objectives of this 24 months project are:

- 1) To strengthen LMHRA capacity as a Governmental organization with mandate to regulate, register and license individuals/entities engaged in the importation, storage, and use of diagnostics for infectious diseases alongside supervision and inspection of access to and use of diagnostics in the frame of clinical trials and clinical research.
- 2) To build LMHRA capacity in revision, design, conduct, analysis and dissemination of research on novel diagnostics for poverty-related infectious diseases with epidemic potential in Liberia (i.e. Lassa, Ebola, HIV, Tuberculosis, Hepatitis C, Malaria, Zika).
- 3) To enhance LMHRA's capacity to establish inter - agencies collaboration through skilful sensitization, mobilization, and active engagement of relevant authorities and civil society in methods of appropriate handling and rational use of diagnostics.

Main results achieved during the first period of the roject

In achieving these specific objectives, a range of meetings, training, research, laboratory upgrading and community engagement activities have been conducted:

A set of 3 Technical Working Groups and Diagnostics Steering Committee meetings have been developed. Composed of LMHRA, SJCH, ISGlobal staff and invited key members to the National Research Ethics Board and Ministry of Health, the developed regulatory framework (guidelines and procedures for registration and licensing) has been revised in order to facilitate a transparent process for investigators and research institutions to apply for revision and approval.

Continuous Communications on Regulatory Framework and information exchange between LMHRA and the Liberian members of parliament, legislators and interministerial committees have been established. Communication technologies such as newsletter, national journal, radio program and LMHRA webpage have been used to update the drafts of developed legislations on new diagnostics for infectious diseases available on the Liberian

A set of 3 three-days hands-on workshops Trainings on Diagnostics Research (Good Clinical and Laboratory Practice, Quantitative Approaches in Diagnostics Research, Fundamentals of Health Research and Medical Ethics) have been held with the participation of ten LMHRA and five SJCH trainees in order to acquire competencies in diagnostics research.

With the aim of consolidating SJCH as a reference laboratory partner for LMHRA, an external consultant has been contracted to facilitate education sessions on new diagnostic technologies refreshment hands-on training on quality control and calibration of RT-PCR. Additionally, the SJCH General Director has been invited to attend an advanced ten-days training in several Spanish health facilities and the RTPCR Unit at the ISGlobal-Centre Esther Koplowitz Laboratory in Barcelona.

During the first period of the project, the IGORCADIA team has been highly committed to promoting equal opportunities in science and research from a gender perspective among participating institutions, contributing to improve the quality of life, the health of women and girls and the participation of women in all the activities developed within the Project. None selection process to become a member of the research team has presented any type of barrier or limitation from a gender perspective. Moreover, a monitoring system has been developed to make sure equal opportunities in within the research team and participants. Power point presentations on Gender Equality have been conducted by IGORCADIA research team in the partners institutions.

Perspectives

The LMHRA and SJCH staff that participated in the regulatory and training activities of the program has shown a great interest and motivation to engage in health research. One of the SJCH trainees have attended international trainings and forums in South Africa: the nursing supervisor attended the three days' workshop on "Good Clinical and Laboratory Practice" in Johannesburg and the Coordinator of Emergency Room participated in the Global Health Research Forum.

In addition, we have established networks with the Food and Drug Authority of Ghana (FDA-Ghana) as a RCORE institution in Clinical Trials in West Africa with the aim to help the LMHRA trainees to performance the evaluation and appropriate use of diagnostics and innovative point-of-care testing, the institutionalization of the importance of accurate and reliable diagnosis, and strengthening their laboratory networks, surveillance and quality.

To sustain the effort and acquired capacities, it is vital to share the progress and outcomes of the project as well as to facilitate networking among other regulatory authorities' representatives and to strengthen and expand collaborations with other Liberian and West African health institutions key diagnostics and microbiology associations.

Expected Impact

The activities carried out in the frame of IGORCADIA will have an impact on three main areas: strengthening LMHRA capacity as a Governmental organization to regulate In vitro Diagnostic Medical devices, the SJCH capacity as a LMHRA reference laboratory, and networking with other institutions involved in Research & Development of investigational medicines and vaccines; and community education and engagement.

Beyond its direct impact on the LMHRA and SJCH, we expect that IGORCADIA will contribute to restore health care, management and research capacities in a country that has suffered enormously from the recent Ebola outbreak. Importantly, we hope it will contribute to help the neighbouring communities regain confidence in the health system and engage in clinical trials that will aim at finding vaccines and/or treatments for emerging infectious diseases that pose a threat to the region, such as Ebola, Marburg or Lassa fever and other highly prevalent infectious diseases such as malaria, HIV and tuberculosis.