LESSONS LEARNT FROM THE DEVELOPMENT OF IVDS REGULATION IN LIBERIA

1. Background

- Accurate regulation of in-vitro diagnostics (IVDs)/medical devices are essentials in the diagnosis, treatment, monitoring and prevention of infectious diseases.
- Development of LMHRA regulatory capacities through the EDCTP-funded project “Improved Governance and Research Capacities in Diagnostics for infectious diseases” (IGORCADIA) is a sine-qua-non.

2. Methodology

- Desk review of regulatory documentations in the region
- “Technical Working Groups”
- “Diagnostic Steering Committee Meetings”
- “Training Programme on Diagnostics Research”
- “Qualitative and quantitative research”
- “RCORE training in FDA-Ghana”
- “Quality Control/Assurance Consultancy”

3. Main Challenges

- Non-coherent framework which does not conform to international standards
- Deficient basic control level
- Limited expertise (analytical and technical)
- Lack of evidence-based policies
- Insufficient infrastructure
- Lack of funding sources and governmental support

4. Current Status:

Regulatory framework/guideline has been developed: “LMHRA Requirements for Market Authorization of In vitro Diagnostics”

5. What’s Next?

- Management approval: basic level controls and enforcement
- Infrastructure improvement
- Develop human resource capacities
- Development and implementation of SOPs
- Implementation of ISO and CLSI standards

Without safe, quality, and accurate diagnosis, the management of suspected patients is guess work

Alexander George 1, Cristina Muñoz 2, Alfredo Mayor 2
1. Liberia Medicines and Health Products Regulatory Authority (LMHRA), Monrovia, Liberia
2. Barcelona Institute for Global Health (ISGlobal), Barcelona, Spain