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"

4. Current Status:

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

6. Prospects

- Continuous regulatory capacity-building
- Strong and harmonized policies with IMDRF and WHO recommendations
- Partnership with national ethics committees
- Basic level control/regulation
- Expanded level control and enforcement

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

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***

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