Clinical Trials Oversight in Liberia: Where are we?

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Outline

• Background
• Legal framework
• The Ebola Experience
• 2017: WHO Global Benchmarking Tool (GBT) self-benchmarking
• LMHRA-Global Health Protection Programme (GHPP): Partnership for capacity building
• Where are we now?
• Conclusion
Background

• Liberia, West Africa, 43,000sq miles, population of about 4.9m people

• On 29th September 2010: The Liberia Medicines and Health Products Regulatory Authority (LMHRA) Act was passed into law
Legal framework: The LMHRA Act, 2010

• Part V, Section 5 of the LMHRA Act, 2010:
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No person/organization shall conduct clinical studies in humans or animals of medicines or health products without the authorization of the Authority.

The conditions for authorization of such clinical studies shall be stipulated in regulations promulgated by the Authority that shall provide for the issuance, renewal, suspension, cancellation and revocation of such authorizations.
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2014-2015: The Ebola Outbreak

• No structures for regulation of CTs:
  ➢ No regulations specifying the approval process and oversight of CTs (including responsibilities of involved institutions)
  ➢ No guidelines for applicants
  ➢ No formal procedures to be followed at the LMHRA
The Ebola Experiences

• The LMHRA role during the outbreak:
  ➢ Receive and evaluate CT applications
  ➢ Ensure regulatory compliance at the CT sites
  ➢ LMHRA received 10 CT applications

• Challenges:
  ➢ Limited capacity for CTA Assessment (pre-clinical, clinical, quality)
  ➢ Effectiveness of the CT oversight: (e.g. AEs reporting, export of biological samples not reported,…)
  ➢ Inspection capacity, logistical challenges
  ➢ No legal framework specifying regulatory CTO actions mandated to LMHRA
  ➢ No structures to conduct CT oversight

• The First CT guidelines for Liberia was developed as the result of the EVD outbreaks to respond to CT applications
2017: WHO GBT self-benchmarking

• Assessment of the maturity level of national regulatory systems for regulation of medicines
• Based on the WHO Global Benchmarking Tool (international standard)
• Maturity level (1-5) estimated based on performance of all institutions involved in regulatory oversight (e.g. regulatory agency, ethics committee, etc.)

• Conclusions:
  ➢ Structures for CT oversight in Liberia were fragmentary
  ➢ Limited human resources
  ➢ Regulatory capacity building is needed in Liberia
LMHRA-GHPP VaccTrain: Partnership for regulatory capacity building

- 2017: The call for proposals for regulatory capacity building in CTs of the Paul-Ehrlich Institut (Sponsored by the GHPP of the German Federal Ministry of Health)

- 2018: Kickoff in Banjul, The Gambia
Regulatory capacity building: The strategy

Capacity building:
- In line with international standards (WHO GBT)
- In communication with international stakeholders (NEPAD AMRH, WHO, AVAREF, etc.)
Regulatory capacity building: The strategy

- Staff Training
- New knowledge sharing and application within NRA

CTO Knowledge and Competences

Remote work
+ Face-to-Face sessions (Country visits)
+ GHPP Sponsorship of LMHRA staff to participate in the Ghana CT RCORE training

Ghana CT RCORE Training:
- Cycle 2018
- Cycle 2019
Achievements from the LMHRA perspective

- 4 country visits (CV) led by Dr. Ivana Škrcnjug, Dr. Ulysse Ateba Ngoa and Dr. Solomon Owusu Sekyere

**Achievements:**

- Established baseline for CT oversight using the WHO GBT
- VaccTrain provided technical support and strengthened CT staff capacity to establish essential CT documents:
  - Developing CT Regulations
  - Reviewing CT Guidelines
  - Developing CT Operational Manual
  - Developing SOPs
  - Developing CTA submission Checklist, and integration of CTA assessment templates as developed by AVAREF
Example 1: Operational manual

• Compilation of the structures applicable to CTs in Liberia
  - Documents drafted as part of the VaccTrain Pilot project and other applicable documents

• Quick oversight of applicable documents and the latest version of templates
Example 2: Implementation of the knowledge gained in external trainings

• **VaccTrain sponsored participation** of three staff members at the CT RCORE training in Accra, Ghana

• **VaccTrain supported LMHRA in development of a SOP** to establish internal mechanisms for implementation of knowledge gained in external trainings (e.g. follow-up expectations)
Where are we now?
Upcoming Phase:
Consensus meeting and implementation

- Drafted Structures (2018-2019)

Liberia/LMHRA implementation phase
- Consensus meeting (CT regulations, CT guidelines) with EC and other stakeholders
- Approval of CT regulations
- Implementation of CT guidelines
- Implementation of SOPs (CTO, Staff-related: documentation of sponsored RCORE trainings)

By August 2019

September 2019 - (July 2020)
Envisaged impact on the maturity of the regulatory system in Liberia

*After implementation of SOPs

Only after establishment and implementation of structures for EC!
Conclusion

- The LMHRA begun CTO activities on very limited resources (HR, scientific capacity for CTA assessment, no well-structured guidelines, no regulations, SOPs, etc.)

- As of the partnership with GHPP VaccTrain, significant improvement have been made over the years:
  - Some trained staff
  - Development of CT documents, integration of AVAREF templates

- Continuous technical support in several other areas still needed (including the EC structures for CT oversight)

- The up-coming implementation phase:
  - Crucial for achieving an effective CT oversight and fine-tuning of the CT operational framework in Liberia in the future
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LHMA
Thank you!!!