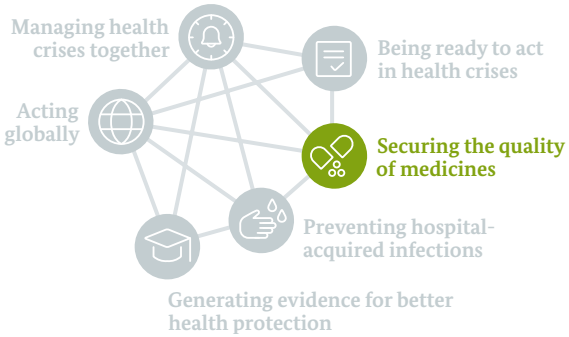


GHP Programme

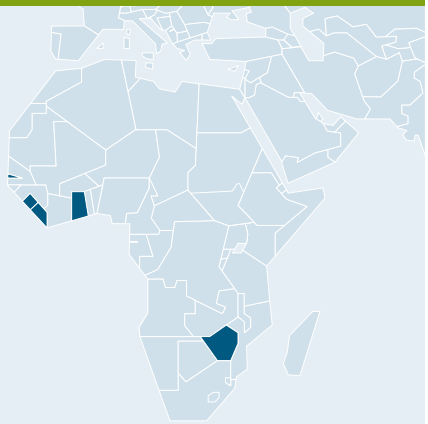
Regulatory Training and Advice in the Field of Vaccines and Biomedical Therapeutics

RegTrain-VaccTrain

Duration
2016–2021

Budget/year
approx. 538,000 EUR

Partner countries
Ghana
Liberia
Sierra Leone
The Gambia
Zimbabwe



Challenges addressed by the project

Many African countries do not have the structures in place to ensure that clinical trial applications are reliably and promptly reviewed, or that they are conducted according to international ethical and scientific standards. Frequently, serious adverse events associated with approved vaccines or medicinal products are not systematically recorded. It is believed that these elements are essential to secure universal access to safe medicinal products. The RegTrain-VaccTrain project strives to be sustainable by considering the different resources available in the partner countries.

Objectives

One of the objectives is to make the regulatory authorities of the less-resourced partner countries aware of their regulatory gaps for clinical trials oversight and drug safety. In cooperation with the RegTrain-VaccTrain, partner countries are developing customised guidelines and processes, and building scientific and regulatory capacity. Partner authorities with well-established regulatory structures are expanding their knowledge through joint fellowships and training courses following the Train-the-Trainer model. They will then share this knowledge with other countries within their economic region or the continent. It is expected that joint training will lead to better interaction and collaboration between the partner authorities in their economic regions. This is ultimately intended to permanently improve universal access to medicines and drug safety, especially vaccines.

Overview of activities

Consultations in Liberia, Sierra Leone, and The Gambia

The RegTrain-VaccTrain team has analysed the regulatory framework in these countries using the WHO's Global Benchmarking Tool, an international standard to assess regulatory capacity. Based on the assessment, the team met on site with each partner authority to define priorities and to prepare a work plan to set up and implement regulatory structures for clinical trials and pharmacovigilance. During the pandemic, the team switched to virtual workshops to continue with their support. RegTrain-VaccTrain is together with the BloodTrain also setting up an e-learning structure to institutionalise the capacity building activities.

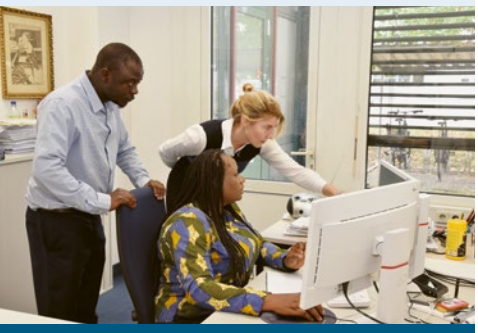
Train-the-Trainer

The RegTrain-VaccTrain is actively working to strengthen the Regional Centres of Regulatory Excellence (RCOREs) for clinical trials and pharmacovigilance in Ghana and Zimbabwe. Under a scheme that started in 2019, regulators from FDA Ghana and MCAZ Zimbabwe were trained on drug safety at the Paul-Ehrlich-

Supported by:

Federal Ministry of Health

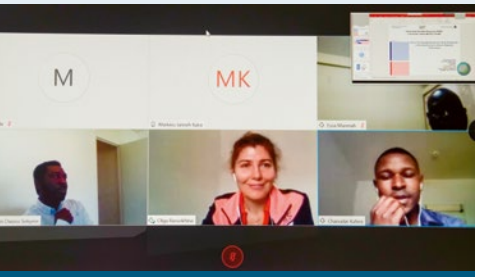
on the basis of a decision by the German Bundestag



Fellow regulators at the PEI are preparing training materials for their host agencies in Ghana and Zimbabwe

Returning Fellows from RCORE-Trainings deliver in-house seminars (Photo ©LMHRA)

Based on the partner countries needs the project develops structures for clinical trials



Virtual support: Conducting a simulation exercise to enhance regulatory preparedness

Photos (unless otherwise indicated) ©PEI

Institut (PEI). The purpose of the programme is to have the guest regulators pass on their regulatory knowledge to fellow regulators at their host agencies and within their economic region sustainably. To achieve this, the guest regulators engaged in parallel activities during the fellowship including participating in a didactics course and preparing training materials. In 2020, the two African regulators from the first Train-the-Trainer programme are acting as facilitators as part of the VaccTrain activities to strengthen regulatory systems in pharmacovigilance. They provide valuable input from the African context, intensify the exchange with the other partner authorities, and consolidate their skills as trainers.

Information platform and networks

The RegTrain-VaccTrain is a technical partner of the African Vaccine Regulatory Forum. It supports the development and implementation of technical documents for clinical trials. The RegTrain-VaccTrain also works closely with WHO and NEPAD to develop strategies to strengthen regulatory cooperation between African authorities.

Partner institutions

- National regulatory authorities in the partner countries
  - Food and Drugs Authority Ghana (FDA), Ghana
  - Liberia Medicines & Health Products Regulatory Authority (LMHRA), Liberia
  - Pharmacy Board of Sierra Leone (PBSL), Sierra Leone
  - Medicines Control Agency (MCA), The Gambia
  - Medicines Control Authority of Zimbabwe (MCAZ), Zimbabwe
- African Union Development Agency – New Partnership for Africa's Development (AUDA-NEPAD), South Africa[1]
- African Vaccine Regulatory Forum (AVAREF)[2]
- Federal Institute for Drugs and Medical Devices (BfArM), Germany
- World Health Organization (WHO), Switzerland

Supporting institution in Germany/Contact

Paul-Ehrlich-Institut
Section G3 | International Coordination/Regulatory Service
Dr Heidi Meyer, Dr Olga Rassokhina vacctrain@pei.de
www.pei.de/en

1 AUDA-NEPAD is working towards establishing a Pan African regulatory system for medicines in Africa
2 Established by the WHO in 2006 to strengthen clinical trials in Africa. It became a continental technical working group of the African Medicines Regulatory Harmonisations (AMRH) Initiative in 2019