**Enhancing Togo's ethical review and regulatory competencies for health research (ERUDIT) Project Summary**

**EDCTP Project Reference:** CSA2017ERC-2017

**Acronym:** ERUDIT

**Coordinating Organisation:** Comité de Bioéthique pour la Recherche en Santé (CBRS)

**Name of Coordinator:** Prof Mireille Prince David

**Participating Organisations:**

• Comité de Bioéthique pour la Recherche en Santé (CBRS)\_ Togo

• Direction de la Pharmacie, du Medicament et des Laboratoires (DPML)\_ Togo

• Council on Health Research for Development (COHRED)\_ Switzerland

• Pharmalys SARL\_Senegal

• Pharma-Ethics (Pty) Ltd\_South Africa

**Project Funded by:** European and Developing Countries Clinical Trials (EDCTP)

**Introduction**

Francophone African countries must catch up in terms of clinical trials and clinical research, and in the ethics review of such research. In terms of clinical trials, health research in general, and ethics review of such research, some countries in Francophone Africa lags.

Togo is a country with limited resources both in terms of infrastructure and human resources for health research management. In addition, research ethics and regulation remains underdeveloped. In order to fill some of the gaps in skills and infrastructure, the Bioethics Committee for Health Research (CBRS), the national research ethics committee, and the Direction de la Pharmacie, du Médicament et du Laboratoire (DPML), under the auspices of ERUDIT consortium (Enhancing Togo's ethical review and regulatory competencies for health research) applied an ethics and regulatory capacity building grant from the European and Developing Countries Clinical Trials Partnership (EDCTP), with the aim of ensuring the CBRS and DPML develop operational knowledge, information system and finance sustainability to operate a professional research ethics review and regulatory service with particular reference to clinical trials and research, vaccine studies, and emerging or re-emerging infectious diseases.

Key partners of the consortium Council on Health Research for Development (COHRED) in Switzerland, Pharma-Ethics in South Africa, and Pharmalys in Senegal and the United Kingdom, the other members of the partnership, joined with CBRS and DPML.

**Objectives**

The overall aim of ERUDIT was to develop operational knowledge, information system and finance mechanism to facilitate effective and professional operations for research ethics review and regulatory service bat CBRS and DPML, focusing mainly on clinical trials and research, vaccine studies, and emerging or re-emerging infectious diseases. Specifically, ERUDIT aimed at :

* Equip CBRS with the RHInnO Ethics platform for research ethics review – with appropriate training and backup.
* Provide training and tele-consultancy services to develop Standard Operating Procedures (SOPs) for the professional administration of CBRS – in a way that such professionalism is immediately available (through virtual REC Administration).
* Provide training in review of clinical trials and clinical research – study design, ethical issues and advanced problems related to emergency situations.
* Provide infrastructure, training and information technology to ensure that the installed RHInnO Ethics can function optimally.
* Support the improvement and maintenance of the dedicated websites for CBRS and DPML.
* Provide access to the growing RHInnO Ethics platform and its resources and services.
* Enable CBRS and DPML to implement financial management to sustain this project.
* Provide support in drafting a code for ethics in human research as the current Code de Sant Publique does not address explicitly human research.
* Provide support to DPML in setting up procedures for the ongoing inspection and enable knowledge transfer.
* Provide assistance for the establishment of a document management system leading to paper free organizations.
* To explore how to best link CBRS to DPML through RHInnO Ethics, for an improved communication and collaboration related to pharmacovigilance aspects.
* Enable on the job training of DPML inspectors with the support from experienced clinical quality assurance experts.

**Outcome**

The implementation of ERUDIT in Togo had the following outcome:

* 1. Over 30 delegates drawn from CBRS, DPML the ministry of health and faculty members of local universities underwent a one-week intensive training in the following modules-
     1. Introduction to SOPs- What are SOPs and why are they important?
     2. Standards and best practice in SOP development
     3. Developing SOPs and templates for CBRS
     4. Institutionalising a REC and SOP development
     5. Institutionalising a REC and SOP development
     6. Research in Public Health Emergencies
     7. Protecting research participants
     8. Ethical considerations in International Health Research
     9. Understanding different research designs and approaches

Understanding and applying Universal Ethics Principles in Health Research

* 1. Delegates from CBRS, DPML the ministry of health underwent a course on
     1. 1-week intensive training course on inspections on regulatory services for clinical trials focus on inspections
     2. SOP writing
  2. Delegates from CBRS, DPML the ministry of health attended and initial training as well as a refresher training course on the use of the RHInnO Ethics system, which enabled them to receive and process research applications using the online review system
  3. CBRS was connected to a global health research information management public portal called HRWeb. With this connectivity, CBRS will be able to contribute important clinical research data, which can go a long way in informing clinical research trends in West Africa, Africa and the globe at large.
  4. A financial sustainability management plan was developed and submitted to CBRS. The plan, which is freely available online (<https://www.cohred.org/wp-content/uploads/2011/05/Guide-for-RECs-on-Financial-Sustainability.pdf>) highlights specific recommendations which RECs can utilise in order to become financially independent and promote sustainability. The same is available in French (<https://www.cohred.org/wp-content/uploads/2011/04/Guide-CER-version-francaise.pdf>)
  5. Following the development of the financial sustainability plan, a ministerial memo (<https://drive.google.com/file/d/1O63OHXi7EVMQ5I8VkVQMTgHCjSsP77Om/view?usp=sharing>) was developed and submitted to the ministry of health. The memo aimed to inform the Togo ministry of health’s senior management about the financial sustainability plan, which identified several mechanisms for promoting the project sustainability. Following the memo, a dedicated annual budget was allocated to CBRS, to support its operation going forward. The memo also initiated a discussions with relevant stakeholders to allow CBRS to utilise 100% of the total revenue collected from the review of research proposals, instead of being allocated 50% of the revenue, as was the case prior to the memo. These initiatives were all part of the recommendations included in the financial sustainability plan, which were summarised in the ministerial memo and have since bore positive results.

**Challenges**

As stated above, COVID 19 had a profound negative effect on the implementation of the project. Specifically, as a result of COVID, some deliverables were delayed, leading to the application of a no-cost extension by the partners. In addition, a RHInnO Ethics training was to be delivered physically had to be done via a virtual platform. Furthermore, physical clinical site inspection visits, which could only be done physically had to be cancelled

**Conclusion**

The ERUDIT consortium brought together partners from West Africa, South Africa and Europe, all of whom worked harmoniously to successfully deliver the project. Despite several challenges experienced during the implementation of the project, including the outbreak of COVID 19 one year after the project kick-off, the partners worked closely to ensure all the key deliverables were met. We believe that some of the deliverables, including the new SOPs, templates and guidelines developed, the knowledge gained from the training provided and relationships build by the consortium are an invaluable resource not only to CBRS and DPML Togo but to the ministry of health, the people of Togo, the West Africa region and the Africa continent as a whole.