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

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

Grant Amount: € 300,000.00

Start Date: Jan 1, 2019

End Date: Jun 30, 2021

Duration (months): 30

Abstract: In terms of clinical trials, health Research in general, as well as in the ethical review of such research, some Francophone African countries are lagging behind others, what is the case for Togo. Togo is a country with limited resources both in terms of infrastructure and human resources for the management of health research.
In order to fill some of the competencies and infrastructure gaps, the "Comité de Bioéthique pour la Recherche en Santé" (CBRS), the national research ethics committee and the Direction de la Pharmacie, du Medicament et du Laboratoire (DPML), the national competent authority in Togo applied to this grant through a consortium. The Council on Health Research for Development (COHRED) in Switzerland, Pharma-Ethics in South Africa and Pharmalys in Senegal and the UK, the other members of the partnership came together with CBRS and DPML to set up ERUDIT:" Enhancing Togo's ethical review and regulatory competencies for health research".
During this first period of the project, CBRS was equipped with the French version of RHInnO Ethics platform for research ethics review and trained thoroughly to ensure optimal use. A support line was also set up.
One focus of ERUDIT is to ensure financial sustainability beyond ERUDIT funding. A week-long training was provided to key people involved in the management of the system.
Prior to the installation of the system, training on research ethics and development of Standard Operating Procedures (SOPs) for RECs was provided to members of CBRS and DPML. The development of CBRS first SOP was initiated during the initial training workshop and finalised later on during several meetings hold by CBRS members.
An interactive workshop was also dedicated to health research inspections as DPML required technical assistance for the setup of SOPs for inspections and training on the planning, conduct and follow up of inspections. The workshop covered aspects such as how to prepare for an inspection and how to develop templates of documents used during inspections. The first inspection SOP was drafted during the workshop and was further

developed by DPML employees. On the field inspections with the support of consultant inspections were scheduled but due to lack of ongoing studies, this activity will take place later.

As part of the management of the ERUDIT project, 16 periodic meetings were organised to increase understanding of the project, the roles and responsibilities of each partner and to discuss practical and logistical aspects at the beginning of the project. These calls allowed the partners to express their difficulties or misunderstandings, to identify the documents required, the translations needed, the actions to be followed for a good coordination of the project. CBRS and DPML have also set up periodic meetings to enhance their routine collaboration during the first period of ERUDIT project.