



Ministère de la
Santé Publique



E D C T P

Project title: « *Strengthening the regulatory framework to upgrade ethical review of clinical research and drugs safety monitoring in Cameroon* » (CSA2017ERC-1911 BREEDSAFCA)

Funder: EDCTP: European and Developing Countries Clinical Trials Partnership

Project duration: 30 months, from November 1, 2018 to April 31, 2021.

Partnering institutions Cameroon:

Ministry of Public Health

- Division of Health Operations Research (DROS) and Department of Pharmacy, Drugs and laboratory(DPML)

Ethics Committee

- National Ethics Committee for Research in Human Health(CNERSH)

Non-Governmental organization partner to MINSANTE

- M.A. SANTE (Meilleur Access aux Soins de Santé)

Context and justification

In Cameroon, health research ethics has made remarkable progress since 2009 till date. This thanks to the political will and with the support of development partners. In 12 years Cameroon has been able to put in place an ethics evaluation system: two out of eight regions have functional regional ethics committees; some basic national regulation have been developed and made available. However, the regulatory aspects on the administrative and ethical evaluation of health research projects still require adjustments as well as the modalities for the functioning of ethics committees and other bodies regulating health research ethics.

Despite the investigation of medicine safety during clinical trials, drugs that are marketed still need to be monitored to insure that during it real live use, it maintain positive risk benefit ratio. The Ministry of Public Health, which is primarily responsible for the supply and distribution of medicines, has set up a pharmacovigilance system to detect and investigate adverse events following authorization to market drugs. This system needs improvements to insure the monitoring of marketed drugs safety in health programs and health facilities.

Overall Project Objectives

Strengthen the regulatory framework for the ethical and administrative evaluation of clinical research and pharmacovigilance in Cameroon.

Specific objectives of the project

- ✓ To update regulatory texts relating to ethics and pharmacovigilance in Cameroon;
- ✓ To assess training needs of investigators involved in health research and of member of research ethics committees in research participants protection;
- ✓ To assess training needs of head of health program and health personnel on pharmacovigilance;
- ✓ To map the training curricula in health research ethics in health training institutions;

- ✓ To train all members of functional ethics review committees and a significant fraction of Cameroonian researchers in research participants protection;
- ✓ To improve the Cameroon coverage in research ethic evaluation by creating two new regional ethical committees and two new institutional ethics committees;
- ✓ To strengthen the national pharmacovigilance system by putting in place pharmacovigilance teams in health programs and in one regional delegation;
- ✓ To provide minimum needed equipment for ethical committees and pharmacovigilance units in health programs.

Expected results

From this project, we expected to improve the coverage and the performances of competent structures in protecting research participants and in monitoring the safety of marketed medicines and vaccines in Cameroon.

Activities implemented within the framework of the project BREEDSAFCA

- **Coordination of the implementation of the project at the Ministry of Public Health**
 - Organisation of the Working Group in charge of the follow-up of the BREEDSAFCA project by Decision n°1457/D/MINSANTE/SG/DROS/DAJC of September 26, 2019;
- **Regulatory instruments revised**
 - The order on the fees for the evaluation of research protocols submitted to the ethics committee to obtain an ethical clearance.
- **Regulatory instruments elaborated:**
 - text on the Organisation of Pharmacovigilance in Cameroon; text on the Organisation of Research in Health in Cameroon; text Organizing the Technical Secretariat of the National Ethics Committee(DROS).
- **procedural Guide elaborated :**
 - the Guide on the Ethics and Administrative Evaluation of Research Protocols(DROS);
- **strengthening of the institutional framework with ETHICS COMMITTEES**
 - The Littoral and West Regional Ethics Committee in the process of creation.
- **Strengthening of the institutional framework with Equipment's for DROS, DPML, CNERSH, MA SANTE.**
 - Donation of : 2 laptops, 12 desktop computers, 13 printers, 8 video projectors, 3 desks, 6 storage cabinets and office consumables.
- **Surveys carried out for need assessment for research participant protection and Pharmacovigilance (MA SANTE)**
 - Training need assessment of researchers and members of ethical committees in Research Participant Protection done by ;
 - Training Need Assessment in drug safety monitoring for heads of health programs and health personnel done;
 - The assessment of curricular needs of health training institutions in research ethics and pharmacovigilance done.