OC - (8378) - REQUIREMENTS FOR THE ETHICAL CONDUCT OF CLINICAL RESEARCH IN CAMEROON, SUB-SAHARAN AFRICA: THE IMPORTANCE OF ACTIVE MONITORING

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Background: Previous evaluation of the state of ethics-regulation in Cameroon/sub-Saharan Africa revealed: law regulating clinical research is lacking; existing committees lack infrastructure and financial support to sustainably review and effectively monitor approved protocols. The present Cameroon National Ethics Committee (CNEC)-EDCTP work aimed at implementing and evaluating active monitoring of clinical research in Cameroon.

Methods: Between 2011-2013, approved clinical trials and protocols involving transfer of biological materials abroad were consecutively monitored. The monitoring tool, a questionnaire on the conformity of key documents e.g. research protocols, ethical clearance, informed consent documents, investigator’s brochure, with a main focus on GCP standards was sent to promoters/investigators ten days prior to the field visit. Teams of two-three monitors, made up of CNEC members and independent consultants, were mobilized per site (hospital/research institute/NGO). Reports with key recommendations were submitted to CNEC for review and approval, to different promoters/investigators, and the Regulatory Authority for action; the monitoring summary was submitted to EDCTP.

Results: Up to 22 site visits were done throughout the country, monitoring about 30 protocols within 11 hospitals, 9 research institutes, a National Programme and an NGO. All sites had ethical clearance and administrative authorization for research; from the registered number of research participants, less than the half signed consent forms were available; other issues were the lack of full involvement of local investigators, inexistence of MTA-DSA with collaborative studies, non-implication of study communities/participants. As educators-consultants, monitors formulated recommendations to investigators, ethics committees and regulatory authority, insisting on the implication of local PI/collaborators with defined percentages of time to be devoted for research and good participatory practice among research communities/participants.

Conclusions: Active monitoring shows some formality in the application of ethical/administrative clearance in Cameroon. However, complex issues raised confirm the necessity of continuous monitoring to meet the high standards, for adherence of clinical research ethics in Cameroon.