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

Background Previous evaluation of the state of ethics regulation in Cameroon 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 project 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 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 mobilised 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 a non-governmental organisation. All sites had ethical clearance and the provision of post-trial benefits. We applied these criteria to collaborative genomics research consortia in Africa (an example of global health research in Africa).

Conclusion The potential for global health research to improve the health capability of countries in Africa will require that attention is paid to research that improves the health of people in Africa and that global health research partnerships identify, first and foremost, what kind of capacity strengthening is required and who is responsible for this activity. African governments and research institutions can play a role to help global health research improve health and health equity in Africa, in ways that are sustainable.