agencies are actively involved in all steps of pharmacovigilance. In sub-Saharan African countries, the lack and weaknesses of national regulatory authorities are being addressed through regional regulatory authorities like AVAREF 2 which aims to oversee pharmacovigilance duties across countries. Informing such initiative about the current practices for the reporting of serious adverse events is needed.

**Methods** We reviewed the reporting of clinical trials performed in CERMEL from 2006–2016. The methods of serious adverse events (SAE) reporting and handling was the main objective of the review.

**Results** The most frequent methods used to reporting SAE for the clinical trials reviewed in Lambarene were: 31% (5/16) paper Case Report Forms (CRF) only, 25% (4/16) electronic case report form (eCRF) without alert, 13% ( 2/16) paper CRF +phone call and 13% (2/16) phone +email or fax+ paper CRF and 6% (1/16) electronic SAE reporting system with alert. Generally, all studies reported SAEs directly to the sponsors who reacted according to their guidelines. Only 2 of 16 studies could involve the Institutional Review Board (IRB), Ethics Committees, and the Data Safety Monitoring Committee (DSMC) and eventually reported to the Regulatory Authorities in the country. The Local Safety Monitoring was involved only in one study which used the eCRF with alert.

**Conclusions** It appears that in the current practices, the reporting and handling of SAEs are mainly done by investigators and sponsors. Although both are the key stakeholders to do so, more active involvement of regulatory authorities is an essential step towards establishment of a pharmacovigilance system and would improve the community engagement towards clinical trials. Electronic reporting with alert system could be one of the methods suitable to involve all partners.

## PA-143 INVOLVEMENT OF STAKEHOLDERS IN THE REPORTING PROCESS OF SERIOUS ADVERSE EVENTS DURING CLINICAL TRIALS IN A SUB-SAHARAN RESEARCH CENTER, LAMBARÉNÉ, GABON

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**Background** The pharmacovigilance of medical products for human use should start during the clinical development and continues after licensure. In developed countries, regulatory