were used to collect views on stakeholders’ perception of benefits, opportunities and challenges of harmonisation.

**Results** Sixty-nine (69) accredited RECs were mapped. All countries had national ethics guidelines and National Research Regulatory Authorities, whose mandates varied across countries. 57% of RECs reviewed local and international research, 43% reviewed local studies only. On average, 91 protocols were reviewed annually across all RECs (range 15 to 200). Membership ranged from 6 to 22 members per REC, with age range of 29 to 75 years.

Annual budget allocation ranged from $3000 to $2.9 million financed through review fees (84%) or/and institutional budget (14%). 71% of RECs had education policy but 41% had members with training in ethics. Review turn-around time ranged from 14 to 90 days. All RECs supported harmonisation and attributed it to improved efficiency, quality and standardised costs.

**Conclusion** Similarities and dissimilarities were noted in the EAC countries’ ethics review frameworks. Harmonisation should consider 1) harmonisation of policy frameworks and tools; 2) institutionalisation of regional joint review mechanisms, 3) standardisation of training and capacity strengthening, 4) Review of the REC operational and financing models.

**OC 8489** CLINICAL DEVELOPMENT OF A THERAPEUTIC VACCINE FOR PREVENTION OF POST KALA AZAR DERMAL LEISHMANIASIS

1Paul Kaye, 2Ahmed Musa, 3Joseph Obbo, 5Margaret Mbuchi, 6Joseph Olobo, 3Asrat Hailu Mekuria, 4Flavia D’Alessio, 5Sophie Houard, 6Odile Leroy, 1University of York, UK; 2IEND, University of Khartoum, Sudan; 3University of Gondar, Ethiopia; 4European Vaccine Initiative, Universitäts Klinikum Heidelberg, Germany; 5Kenya Medical Research Institute, Nairobi, Kenya; 6Makerere University, Kampala, Uganda

**Background** Leishmaniasis represent a complex of human diseases, with 350 million people at risk of infection worldwide. Although the potential benefits of vaccination have been well-recognised, no human vaccine is registered. Post-kala azar dermal leishmaniasis (PKDL) is a chronic skin disease often following treatment for visceral leishmaniasis (VL). In addition to affecting quality of life, evidence suggests that PKDL patients may also act as reservoirs for VL transmission. Hence, PKDL vaccines may have a significant impact on disease burden. We recently developed a third-generation adenoviral vaccine for leishmaniasis (ChAd63-KH) that has been evaluated for safety and immunogenicity in healthy volunteers (Osman et al, 2017). ChAd63-KH is currently being evaluated for safety as a therapeutic in Sudanese PKDL patients, with a phase Ib/II RCT starting in late 2018. With EDCTP funding, we are initiating a new phase IIa/IIb study (PREV_PKDL) to determine whether ChAd63-KH can prevent PKDL development.

**Methods** In PREV_PKDL, we will conduct an open-label phase IIa safety study, followed by a placebo blinded, phase IIb RCT. Safety and clinical response represent primary outcome measures, and immunogenicity is a secondary outcome measure. In addition, working across the four countries of Leishmaniasis East Africa Platform (LEAP), we will use deep phenotyping methods to study the immune status of patients before and after treatment for VL to understand why PKDL development is limited to specific geographic regions. This work, and other research in the region, will be supported by the creation of a new flow cytometry ‘centre of excellence’ within LEAP.

**Results** An update on the progress of our current therapeutic trial in PKDL patients will be provided.

**Conclusion** PREV_PKDL represents an important step in the clinical development of ChAd63-KH and will help develop capacity to support future vaccine and drug trials for leishmaniasis in the East Africa Region.