

and DHA-PQ, respectively. The PCR-corrected efficacy rates were estimated at 99.8%; 99.7%; 99.9%, at day 28% and 99.3%; 99.7%–99.9% in PYR, ASAQ and DHA-PQ, respectively.

Conclusion The parasite clearance times were comparable among the three ACT arms of treatment and their efficacy was comparable and higher than 99%. There was no delay in parasite clearance time (PCT \geq 72 hour).

OC 8465 THE DEVELOPMENT OF A CONJUGATE VACCINE AGAINST GROUP B STREPTOCOCCUS: AN AFRICAN PERSPECTIVE

Seanette Wilson*, Patrick Tippoo. *The Biovac Institute, Cape Town, South Africa*

10.1136/bmjgh-2019-EDC.18

Background *Streptococcus agalactiae*, or group B streptococcus (GBS), is a gram-positive streptococcal bacterium that is well-recognised as one of the leading causes of infant death, particularly in the early neonatal period (the first week of life). An estimated one in five pregnant women around the world carries GBS bacteria in their gastrointestinal or genitourinary tracts and vertical transmission from colonised mothers can lead to invasive disease in their offspring. A recent study conservatively estimated that out of 410,000 GBS cases globally every year, there are at least 1 47 000 stillbirths and infant deaths. Despite being home to only 13% of the world's population, Africa has the highest GBS disease burden, with 54% of estimated cases and 65% of stillbirths and infant deaths.

An effective GBS vaccine, given during pregnancy, is a promising strategy to protect against GBS disease. Currently, no licensed vaccine exists to prevent it, but scientific evaluation of feasibility is favourable. The leading vaccine candidates are capsular polysaccharide-protein conjugate vaccines. Evidence suggests maternal immunisation with a safe and effective GBS vaccine may reduce the disease risk in neonates and young infants.

The Biovac Institute was established as a private-public partnership and is the only Southern African vaccine manufacturer. Located in Cape Town, South Africa, Biovac's mission is to become a leading vaccine developer and producer in South Africa to increase capacity in Africa which only has four other vaccine manufacturers.

In collaboration with PATH, an international health organisation, and other partners, Biovac is developing a multivalent conjugate vaccine against GBS. The first stage of the project involves the development of biopharmaceutical manufacturing processes and analytical tests, the preparation of clinical trial product, and execution of a first-in-human clinical trial.

This presentation will provide an overview of the project, progress to date, and the path to commercialisation.

OC 8469 REVIEWING INVESTIGATIONAL PRODUCT'S QUALITY ASSURANCE DOCUMENTATION IN MAJOR CLINICAL TRIAL REGISTRIES FOR POST-MARKETING CLINICAL TRIAL STUDIES

^{1,2}Joachim Doua, ^{1,3}Hanneke Dominicus*. ¹*Consortium for African Regulatory Expertise Development (CARED), The Hague, The Netherlands;* ²*Johnson and Johnson, Brussels, Belgium;* ³*Dominicus Medicus Consultancy, The Hague, The Netherlands*

10.1136/bmjgh-2019-EDC.19

Background The proven worrisome quality of medicines marketed in developing countries also affects clinical trials (CTs) as they may be used as Investigational Medicinal Products (IMPs). By regulation, CT sponsors should assure IMP's quality and describe their quality measures in CT protocols that should be registered in a CT Registry (CTR). To check compliance with this regulation, we reviewed major CTRs to assess the availabilities of data fields on IMP quality for post-marketing CTs.

Methods Two reviewers independently assessed English versions of CTRs of International Committee of Medical Journal Editors (ICJME) and WHO platforms in July 2017. Each CTR was checked for availability of data fields on: brand name; manufacturer's name; regulatory approval status; approving regulator; manufacturer's compliance with Good Manufacturing Practices (cGMP); and quality testing (IMP appearance, impurities, microbial contamination, dosing). In case of discrepancy, consensus was sought.

Results Of 19 CTRs identified, 8 and 6 belonged to WHO and ICMJE, respectively, and 5 were equally part of both platforms. All CTRs had an 'intervention' data field to capture data on IMPs and IMP comparators. Unlike all others, the Canadian CTR used 'drug name' rather than 'intervention'. Only the EU CTR had data fields for 'manufacturer's name', 'product approval status', and 'approving authority'. None of the CTRs had data fields on 'cGMP' or 'quality testing'.

Conclusion None of the CTRs of ICMJE and ICTRP has adequate data fields to establish that the source of post-marketing IMPs is of assured quality. This is astonishing given the extensive requirements in WHO and ICMJE guidelines. The gap of quality assurance fields should be bridged by adding them to CTRs. Specifically, IMP quality testing should be conducted before, during, and after clinical trial completion. Until adoption of these measures, EU-CTR should be favoured for registration of CTs conducted in developing countries.

OC 8474 ASSESSMENT OF ETHICS REVIEW FRAMEWORKS FOR HEALTH RESEARCH IN EAST AFRICA FOR PURPOSES OF HARMONISATION

¹Gibson S Kibiki, ¹Novat Twungubumwe*, ²Francis Kombe, ³Carel IJsselmuiden, ⁴Prince N Bahati, ⁴Anatoli Kamali, ¹Jean De Dieu Ngirabega. ¹*East African Health Research Commission, Burundi;* ²*Council on Health Research for Development, Kenya;* ³*Council on Health Research for Development, Geneva, Switzerland;* ⁴*International AIDS Vaccine Initiative, Nairobi, Kenya*

10.1136/bmjgh-2019-EDC.20

Background Capacity in health research ethics review is key in Africa, given the increase in research activities, complexity, and use of advanced technologies. Harmonising ethics review frameworks can address challenges attributable to these complexities. Establishing an effective harmonised framework that is optimum or protection of the research subjects requires assessment of review capacity.

The East African Health Research Commission commissioned a study to assess the capacity of Review Ethics Committees (RECs) in the East African Community (EAC) countries, as a step towards strengthening and harmonising the regions' capacity and review frameworks.

Methods A desktop review of documentation (national and institutional guidelines, policies and SOPs) was conducted in five EAC countries. Semi-structured questionnaires were used to collect data from key informants. Qualitative interviews

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 8477 MAKING RESEARCH EASIER, BETTER AND FASTER THROUGH KNOWLEDGE SHARING AND BUILDING COMMUNITIES OF PRACTICE

Leandro Abade. *The Global Health Network, UK*

10.1136/bmjgh-2019-EDC.21

Background The Global Health Network improves the health research capacity of low- and middle-income countries (LMICs) by facilitating know-how and knowledge exchange between organisations, disease areas, regions and roles. We show how we use the sharing phenomenon to transform and drive health research in resource-limited settings.

Methods We harnessed cutting-edge technology that facilitates engagement of medical researchers and healthcare professionals in low-resource settings and creates opportunity for knowledge exchange and capacity development in global health. We built highly functional digital communities of practice (CoPs) that serve as learning and sharing tools for researchers, and a gateway for sharing experience about disease research. These CoPs are intertwined with regional activities such as training workshops with health care professionals, which helps to enhance engagement and impact.

Results We disseminate resources with collaborators to enable research in LMICs via 37 CoPs. The data derived from these CoPs is used to identify knowledge-gaps in research capacity, as well as a guide to the development of resources and tools, such as standardised outcome measures. The network has developed 25 free peer-reviewed e-learning courses covering a wide range of topics, as well as high-quality professional development tools. We highlight the WHO-TDR Professional Development Scheme that tracks and guides training and career development. The network has trained over 33 500 professionals (with >400 k courses taken) across 119 LMICs

on the principles of good clinical practices ensuring the safety of research participants and the integrity and validity of research data.

Conclusion The Global Health Network is enabling research in areas where data is missing by providing tools, training, and resources whilst supporting and training research teams. The next step is to widen this impact and invite new researchers to drive and enable more and better clinical research in places and situations where evidence is still woefully lacking.

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

¹Paul Kaye, ²Ahmed Musa*, ⁶Joseph Olobo, ⁵Margaret Mbuchi, ³Asrat Hailu Mekuria, ⁴Flavia D'Alessio, ⁴Sophie Houard, ⁴Odile 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

10.1136/bmjgh-2019-EDC.22

Background The 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 IIb 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.