knowledge score among trainees ($p<0.05$). The project has also provided a platform for sharing experiences and maintaining partnerships with regional and international institutes in addition to provision of technical support for newly established RECs.

Conclusion We believe that the array of activities conducted through this project had enhanced the governance, coordination, feasibility and, efficiency of the ethical review system in Sudan.

OC 8717 TRANSFER OF LEADERSHIP, WHAT DO WE NEED?

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Background The Pan African Consortium for the Evaluation of Anti-Tuberculosis Antibiotics (PanACEA) was designed to build clinical tuberculosis (TB) trial capacity whilst conducting clinical trials investigating novel and existing agents to shorten and simplify TB treatment. One of the objectives of the programme is to foster leadership development in sub-Saharan TB-endemic countries to move leadership to African partners in the PanACEA research programmes.

Methods and results In PanACEA 1 the participation of the sites on the consortium board was important to foster leadership development. African investigators now make up a large part of the consortium leadership and are actively developing new concepts. Delegates of the sites visited the annual PanACEA General Assembly meetings, where they could gain knowledge, actively participate in the meetings and discussions and network with others from the TB research community. Various sites participated at TB research community conferences (e.g. CROI, Lung Health Meeting) where PanACEA members gave presentations and could collaborate with other TB trial networks.

In PanACEA 2 all clinical trials are co-led by a European established researcher and an African Principal Investigator (PI), to ensure that African scientists are trained and mentored to lead in every aspect essential to clinical trial delivery, from trial and data management to statistical analysis and trial design, and from financial management to laboratory science. The capacity development cores, which serve as operational support for all PanACEA studies and provide high level oversight, also use the European and African countersystem, including senior and junior co-chairs among the African trial sites.

An example of leadership transfer is a large EDCTP application for the development of a new compound in MDR TB (FACE-MDR-TB) in which Stellah Mpagama is the lead applicant.

Conclusion The PanACEA consortium has actively facilitated a transfer of leadership programme which may be successful in future consortia.

OC 8718 WHAT DID WE LEARN FROM PANACEA 1 CLINICAL TRIALS?

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Background The Pan African Consortium for the Evaluation of Anti-Tuberculosis Antibiotics (PanACEA) was designed to build clinical tuberculosis (TB) trial capacity whilst conducting clinical trials on novel and existing agents to shorten and simplify TB treatment. One of the objectives was to conduct, mentor and monitor observational and clinical studies at sites in 6 Sub-Saharan TB-endemic countries (Gabon, Kenya, South Africa, Tanzania, Uganda and Zambia)

Methods Learning through experience. All centres in the 6 countries self-assessed their requirements for capacity development in the following fields: a) clinical staff availability and experience; b) TB laboratory infrastructure and staff; c) safety laboratory infrastructure and staff; d) clinical site facilities and equipment; e) pharmacy facilities and staff; IT facilities; and f) overall training needs of site personnel.

Results From March 2011 – June 2014, we conducted four epidemiological studies (characterising TB patient populations in preparation for future studies) and five phase II studies (GCP standard intervention trials).

By working together in epidemiological and clinical trials, the sites identified their needs for resources and training as well as developing capabilities to perform independent large-scale TB clinical trials beyond PanACEA-initiated trials. Through the ReMoxTB study, for example, laboratories were brought to an international standard for safety and mycobacterial expertise. Furthermore, through developing skill-sets related to EBA studies, sites have since then attracted other sponsors for further studies.

Sites could be mentored to perform GCP-compliant clinical TB trials that is built on sound physical infrastructure, training and strong on-site leadership.

Conclusion The learning-by-doing approach meant that staff could be trained whilst acquiring new core competencies and revealing operational gaps. Our experience of conducting TB trials within an environment of mentoring, networking and training has provided a platform for establishing future sustainable research centres that has capacities to conduct highly regulated studies.

OC 8721 WANECAM II – A CLINICAL TRIAL PROGRAMME TO ASSESS SAFETY, EFFICACY AND TRANSMISSION-BLOCKING PROPERTIES OF A NEW ANTIMALARIAL KAF156 (GANAPLACIDE) IN UNCOMPLICATED MALARIA IN WEST AND CENTRAL AFRICA

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Background Despite major progress in the past decade, malaria remains a major public health problem in sub-Saharan Africa. West and Central Africa account for nearly 2/3 of the burden currently attributable to falciparum malaria. Artemisinin-based

combination therapies (ACT) are a cornerstone of our strategy for controlling and eventually eliminating malaria. However, reduced responsiveness/resistance to artemisinin derivatives and to ACTs, an increasing problem in South-East Asia is a major concern. It is of utmost importance to develop new antimalarial drugs from novel chemical classes that can replace ACTs. KAF156, an imidazolepiperazine, is a leading candidate in the antimalarial drug development pipeline. Combination of KAF156 with a Solid Dispersion Formulation of lumefantrine (LUM-SDF) is expected to be fast acting, fully curative, improve patient adherence and can potentially reduce malaria transmission.

Methods WANECAM II proposes to advance the clinical development of KAF156 through clinical trials in adults and children, with integrated capacity building and infrastructure development activities. The trial programme will be undertaken in the context of networking, team-building, leadership development and community engagement schemes that will involve intra-European, European-African and intra-African collaborative activities. WANECAM II will accelerate the clinical study of children less than 2 years of age which are the key target for new antimalarial treatments.

Results By the end of the project, the results are expected to contribute to the registration of KAF156/LUM-SDF through stringent regulatory health authorities, increase biomedical research capacity in the consortium and effectively promote networking among the respective teams. A new clinical research team in Niger, a grossly underrepresented country in the African research landscape, will be developed and further increase capacity and infrastructure in the consortium.

Conclusion Providing a new antimalarial drug combination that does not contain an artemisinin derivative and is effective against resistant *P. falciparum* strains as well as gametocytes and that is likely to be taken in 3 or fewer single doses will be a major advance in the field. The new combination of KAF156 with LUM-SDF is expected to provide such major advance upon successful conclusion of the WANECAM II project.

OC-8722 THE GENERATION AND TESTING OF A GENETICALLY ATTENUATED MALARIA PARASITE (GAP) VACCINE

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10.1136/bmjgh-2019-EDC.44

Background Immunisation with radiation-attenuated *Plasmodium falciparum* sporozoites (SPZ) (Sanaria PfSPZ Vaccine) can protect >90% of vaccinees against controlled human malaria infection (CHMI) and protects against naturally-transmitted *P. falciparum* in Africa for at least 6 months. Immunisation with sporozoites of genetically attenuated parasites (GAPs), which completely arrest after liver-cell invasion can be potentially safer and more potent than irradiated sporozoite vaccines. As part of a collaboration between two Dutch research groups (LUMC and Radboud University) and the US company, Sanaria, we describe the generation and first-in-man testing of a GAP vaccine,

Methods We screened single and multiple gene deletion parasites in order to identify parasites that can invade hepatocytes but are unable to complete liver-stage development. Informed by rodent studies we created *P. falciparum* double gene-deletion mutant, Δ*b9*Δ*slarp*; sporozoites of this line were infective to human hepatocytes *in vitro* and to humanised mice but they completely arrest after invasion. PfΔ*slarp*Δ*b9* PfSPZ (Sanaria PfSPZ-GA1 Vaccine) was manufactured in compliance with cGMPs and released for human clinical trials in the EU under a conditional release GMO license. This GAP vaccine was used to perform phase I (safety) and phase 2a (efficacy) clinical CHMI trial in the Netherlands.

Results In a dose escalating phase I clinical trial, the vaccine showed an excellent safety profile. All adverse events related to the vaccine were mild (grade 1). Based on this indication of safety, vaccine efficacy was examined by CHMI; 48 subjects were subsequently enrolled into phase 2a study and were immunised with either PfSPZ-GA1 or PfSPZ Vaccine or saline placebo.

Conclusions In conclusion, PfSPZ-GA1 Vaccine is the first injectable genetically attenuated malaria vaccine assessed in humans. The accomplishment to manufacture, obtain regulatory approval and to demonstrate an excellent safety profile for this vaccine is unprecedented and holds a promise for PfSPZ vaccines with increased potency.

OC-8723 CREATING AND ENHANCING TRUSTWORTHY, RESPONSIBLE AND EQUITABLE PARTNERSHIPS IN INTERNATIONAL RESEARCH

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Achieving equity in international research remains a crucial concern of the 21st century. Despite initiatives by international organisations on governance frameworks and standards to guide research conduct, such efforts remain disparate and lack focus. In an interdisciplinary collaboration between multi-level ethics bodies, policy-advisors, civil society, funders, industry and academic scholars, the TRUST project combines long-standing, highly respected efforts to establish international governance structures along with networking opportunities between Europe, sub-Saharan Africa and Asia.

The goal of TRUST is to catalyse a collaborative effort to improve adherence to high ethical standards in global research. The strategic outputs of the project encompass a set of ethics tools developed through participatory engagement traversing all continents: (i) a global code of conduct for funders, (ii) a fair research contracting web-tool (iii) and a compliance and ethics follow-up tool.

Since project inception in October 2015, the TRUST consortium has a) created an international network on global research ethics governance to identify generic risks of exporting non-ethical practices; b) established funder and industry platforms; c) identified typical case studies of exporting non-ethical practices and reported on lessons learnt; d) developed a global code of conduct that will be used by the European Commission and like-minded funders to foster ethical research and equitable partnerships; e) designed an online Fair Research Contracting tool to empower vulnerable populations under non-ideal conditions; and f) drafted a compliance and ethics follow-up tool, for conditions of high vulnerability.

TRUST envisages to make a tremendous impact on three major issues: a) enhancing the rights of indigenous people who have borne a disproportionate burden of research whilst