(CI:0.47–0.93), p=0.02] were statistically not associated with LTBI positivity. Overweight and obese DM patients had increased odds of LTBI [AOR=1.85 (1.02–3.35) p=0.04 and AOR=2.18 (1.19–3.97) p=0.01] respectively. Known factors such as current BCG scar, smoking, or alcohol use were not associated with LTBI in this population.

Conclusion People with DM in East Africa are at a high risk of LTBI. Early detection and treatment of LTBI in this population could help prevent the progression to active TB and reduce morbidity and mortality associated with TB in people with DM.

Funding: EDCTP

OA-408 CLINICAL TRIAL CAPACITY BUILDING FROM SCRATCH: THE WANECAM 2 EXPERIENCE IN NIAMEY, NIGER

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Background The West African Network for Clinical Trials of Antimalarial drugs second edition (WANECAM2) is an Africa-Europe consortium funded by EDCTP2. In collaboration with Novartis and Medicines for Malaria Venture WANECAM2 is contributing to the development of KAF156-LUM SDF and improving clinical studies capacity in the sub-Region. A novel team was identified in Niger, where clinical trial capacity is lagging and was targeted for focused capacity building.

Methods A series of trainings in clinical trial procedures, GCP and GLP were provided by the MRTC-team in July 2019 in Bamako, Mali. A second GCP training was done on site in Niamey, Niger by the MRTC in November 2019 where the entire Niger team participated. Two Niger Biologists visited the MRTC for training and certification in August 2022 while one physician received advanced training in clinical trial procedures, embedded in one of the Mali trial sites. Three nurses were trained on the REDcap platform on medication data entry. One PhD student and one MSc student were registered at USTTB, Mali. Site visits of WANECAM2 teams in Burkina-Faso were organized for the Niger leadership.

Results From November 2019 to December 2020, with on-site assistance from two experienced physicians and one laboratory certified technician from Mali, the Niger team conducted a Phase IV in vivo study on the efficacy of Artesunate-Pyronaridine versus Artemether-Lumefantrine and enrolled 240 participants. A second study on biological parameters completed in May 2022 with a total of 1052 participants enrolled. Quality control and data analysis are underway. A new building was refurbished and fully equipped.

Conclusion A new study team and infrastructure was built from scratch in Niger through South-South collaboration and is ready to contribute to an upcoming Phase III trial.

Funding: WANECAM2 which is part of the EDCTP2 (RIA2017T-2018 WANECAM2).

OA-442 LEGISLATIVE, EDUCATIONAL, TRAINING, INSTITUTIONAL AND SOCIAL IMPACT EVALUATION OF THE BERC-LUSO PROJECT IN THE PORTUGUESE-SPEAKING AFRICAN COUNTRIES

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Background The Biomedical Ethics and Regulatory Capacity Building for Portuguese Speaking African Countries Project (BERC-Luso) was a four-year initiative that aimed to enhance biomedical ethics and regulatory capacities in Angola, Cape-Verde, Guinea Bissau, Mozambique, São Tomé and Príncipe, and Portugal. The project established a network of National Ethics Committees (NCEs), National Regulatory Authorities (NRAs), and experts in biomedical research, developed a comparative legislative study, and created educational programs to promote capacity building. The digital repository in Portuguese language served as an example for similar projects and supported complementary actions beyond the project's term.

Methods A set of indicators was developed to measure the project's impact, and the evaluation was carried out through public and grey literature and event reporting. The indicators were linked to concrete actions that leveraged institutional, legislative, and capacity-building development. Score points were attributed to each indicator, with calculation of score mean values.

Results In all partner countries, a high level of success (78.59%) was achieved by meeting the goals set at the beginning of the project via the roadmap. A total of 311 activities were developed, impacting at least 3,848 professionals from different backgrounds. Over 172 hours of training were delivered, and the project registered mass dissemination through television broadcast, radio, and media in at least six countries.

Conclusion Overall, the BERC-Luso Project had a significant impact on every participating country, visible through the long-lasting effects of the successful implementation of the bottom-up and top-down approaches. The project trailblazed capacity building in ethical and regulatory revision in the partner countries, but there is still a need for further investment in legislative, institutional, and training levels to reinforce the implementation of best practices.