

inflammatory markers, analysis has been completed and will be available timely.

**Conclusion** In this phase 2 trial, there was no evidence to suggest that administering two live attenuated rVSV-ZEBOV Ebola and Varicella, was associated with a risk of rheumatic diseases in children. The noted pseudo-signs of rheumatic diseases like arthralgia and body ache were strongly linked to Malaria infection. These findings provide reassurance regarding the safety profile of rVSV-ZEBOV-GP Ebola and varicella concerning rheumatic diseases in children.

**PA-539** **DEVELOPING HANDS-ON SKILLS ON TUBERCULOSIS SPONSOR RESPONSIBILITIES AND CLINICAL TRIAL MANAGEMENT FOR END-TB IN SUB-SAHARAN**

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**Background** The END TB strategy recommends scaling up of research training and capacity by growing the workforce of scientists in tuberculosis (TB) endemic settings skilled in “development and rapid uptake of new TB tools and “interventions” and “research to optimise implementation and impact”. The SimplicITB consortium aimed to develop the skills, confidence and international competitiveness of African research leaders engaging in TB while extending network of African sites capable of performing high quality clinical trials in TB.

**Methods** Through co-leadership and partnership with St Andrews University, University College London from United Kingdom; Radboud University Medical Center-The Netherlands and TB Alliance-United States mentorship was provided to the senior clinical research fellow and clinical research & development fellow based at Kibong'oto Infectious Diseases Hospital in Tanzania to execute sponsor and trial management responsibilities for a new clinical trial of anti-TB therapy to be delivered in four African countries: Gabon, Malawi, Mozambique and Tanzania.

**Results** From January 2022- April 2023, achievement in capacity development include design of the potential regimen for a phase III TB clinical trial, and development of the protocol titled: “A pragmatic trial with optimized dose of rifampicin and moxifloxacin for the treatment of drug susceptible pulmonary tuberculosis (OptiRiMoxTB)”. The Operational team meeting was successfully formulated comprising of two categories i) sponsor category with international principal investigators as co-chairs, trial manager and associated core groups including biostatistics and data management, pharmacy and drug management, microbiology and biomarkers, finance and administration and ii) Trial sites each bringing at least the site PI, and site coordinators. Trial-governance including the data safety monitoring and steering committees are set. All

sites have submitted ethical and regulatory clearance to their respective bodies and authorities.

**Conclusion** Despite challenges, the preparatory phase has completed and enrolment of participants expects to start in the second quarter of 2023.

**PA-543** **EVALUATION OF HOST SERUM BIOMARKERS FROM SUCCESSFULLY TREATED TB PATIENTS PRESENTING WITH OR WITHOUT PERSISTING LUNG INFLAMMATION – PRELIMINARY FINDINGS OF STATINTB TRIAL**

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**Background** Despite the availability of anti-TB treatment, successfully treated TB patients remain with persisting lung inflammation regardless of HIV status. Lung inflammation has been linked with robust or imbalanced host immune responses which exacerbate tissue necrosis. Soluble host biomarkers have been shown to correlate with the development of lung inflammation at different stages of anti-TB treatment which further affect sputum conversion in these patients.

In our ongoing StatinTB trial (RIA2017T-2004; NCT04147286), we evaluate safety and efficacy of 40 mg atorvastatin to reduce persistent lung inflammation after TB treatment in HIV-/HIV+ adults measured by 18F-FDG-PET/CT. Here we aim to explore the expression profile of host serum biomarkers from successfully treated TB patients with or without persisting lung inflammation.

**Methods** Study participants were screened for sputum conversion at month-4 and month-6 of anti-TB treatment. Enrolled participants were subjected to PET/CT scan, where Arm A=TLG<50SUbw\*ml (minimal lung inflammation) and Arm B=TLG≥50SUbw\*ml (persisting lung inflammation). A total of 71 participants (Arm A=42, Arm B=29) were evaluated in this study. Serum samples were collected after 1-week washout period following completion of anti-TB treatment. A panel of 48 biomarkers were evaluated using Luminex multiplex platform (Bioplex200).

**Results** Twenty soluble biomarkers were differentially expressed between Arm A (TLG<50SUbw\*ml) and B (TLG≥50SUbw\*ml). These included 9 pro-inflammatory biomarkers, 1 anti-inflammatory cytokine, 5 growth factors, 2 pleiotropic mediators and 3 chemokines. Using ROC curve, 14 biomarkers were identified as potential individual candidates to distinguish between Arm A and Arm B with AUC ranging between 0.702–0.833 where sensitivity ranged between 58.6–69.0% and specificity ranged between 71.4–81.0% at specific cut-off values.

**Conclusion** This study highlights that successfully treated TB patients remain with persisting lung inflammation. These patients further present with different soluble biomarker profiles which may be driven by lung inflammation.