ScreenTB

Evaluation of host biomarker-based point-of-care tests for targeted screening for active TB

FACT SHEET

ScreenTB

Acronym
ScreenTB

Full Title
Evaluation of host biomarker-based point-of-care tests for targeted screening for active TB

Programme
EDCTP2/2nd European & Developing Countries Clinical Trials Partnership Programme

Grant Agreement Number
DRIA2014-311

ABSTRACT

Recently, new recommendations regarding screening for active TB have been formulated and these include a focus on high TB prevalence areas, people living with HIV infection and populations with difficult access to efficient TB diagnostic services, such as access to GeneXpert testing. Our proposed project builds on extensive experience gained during EDCTP I, is based on strong and very promising host biomarker data and on in-depth experience with point-of-care (POC) implementation of user-friendly lateral flow assays (LFAs).

The proposal addresses the important topic of screening for active TB, which would significantly speed up and streamline diagnostic approaches in resource-limited settings. We have identified a six-marker diagnostic signature for active TB with sensitivity of 89% and specificity of 75%, regardless of HIV status and are proposing to implement testing of this signature through rapid, laboratory-free POC LFAs with the capability to measure multiple markers simultaneously.

The proposed LFA device utilizes novel, nano-sized upconverting phosphor (UCP) reporter particles as quantitative read-out with excellent sensitivity and robustness; the UCP label is not hampered by common auto-fluorescence background and does not fade over time. The LFA can be adapted for measurement of markers in finger-prick blood, which will further enhance its POC utility. Our non-interventional trial will recruit 800 people with symptoms suggestive of active TB, regardless of HIV infection status, and across five African countries. UCP-LFA test results will be compared to gold standard tests and established project-specific case definitions.

The successful implementation of a sensitive, cost effective screening test with test performance similar to our current biosignature would streamline diagnostic programs in resource-limited settings and could decrease unnecessary referrals for GeneXpert testing

by 75%. Additionally, we will continue to build significant African clinical trial capacity by hosting workshops on clinical trial and laboratory procedures during our annual meetings and by supporting the promising early and mid-career African scientists through a mentorship program and by improving South-South and South-North networking.

Duration
40 months (01/04/2016 - 31/07/2019)

Project Funding
2.998.834 EUR

Coordinator
Prof Gerhard Walzl
Stellenbosch University
Faculty of Health Sciences
Division of Molecular Biology and Human Genetics
Department of Biomedical Sciences
Francie van Zijl Drive
PO Box 19063
Tygerberg 7505, South Africa
Tel: +27 21 9389158
Fax: +27 21 9389476
Email: gwalzl@sun.ac.za

Partners
- Medical Research Council, The Gambia
- Armauer Hansen Research Institute, Ethiopia
- Makerere University, Uganda
- University of Namibia, Namibia
- Academisch Ziekenhuis Leiden, The Netherlands
- London School of Hygiene and Tropical Medicine, United Kingdom
- European Research and Project Office GmbH, Germany
- LINQ management GmbH, Germany

Project Management
Julia Buech
LINQ management GmbH
Phone: +49 (0)30 300 96442
Email: j.buech@linq-management.com