

TriageTB

Field evaluation of a point-of-care triage test for active tuberculosis



Acronym

TriageTB

Full title

Field evaluation of a point-of-care triage test for active tuberculosis

Programme

EDCTP / European & Developing Countries Clinical Trials Partnership Programme

Contract number

Grant Agreement N° RIA2018D-2499

ABSTRACT

The goal of TriageTB is to field-validate a rapid point-of-care triage test for active tuberculosis (TB) that can be conducted in a laboratory-free manner. Such a test could transform the TB diagnostic landscape.

Most of the experts from Africa and Europe behind this project have successfully worked together in the two previous EDCTP-funded initiatives AE-TBC (*African European Tuberculosis Consortium*, July 2010 – December 2013) and ScreenTB (*Evaluation of host biomarker-based point-of-care tests for targeted screening for active TB*, April 2016 – July 2019). They have now teamed up with the Foundation of Innovative New Diagnostics (FIND) to improve the test further and ensure its global applicability and prepare its commercialisation. The passionate members of the team have very complementary skills and work with a shared goal: to make a real difference in the lives of patients.

TriageTB started in October 2019 and will run for four years. The project's vision is to develop a triage test, or rule-out test, with low complexity that can be performed at the point-of-care in a laboratory-free manner by minimally trained health care workers. The test would identify patients who have the highest risk for active TB. It would quickly rule out the majority of patients who do not suffer from TB but have other respiratory illnesses such as acute upper or lower respiratory tract infections or exacerbation of chronic obstructive pulmonary disease. A positive test result would indicate a high likelihood of active TB and a) allow health workers to focus their attention on this smaller number of patients and b) potentially increase adherence of patients as well as primary health care workers to the diagnostic workup process, which normally includes return visits for GeneXpert or culture results. Improved adherence would allow for a definitive diagnosis and quicker initiation of treatment.

More specifically, TriageTB aims to refine and prospectively evaluate the performance of a POC multi-biomarker test (MBT) as triage test on fingerstick blood using upconverting phosphor technology at three African sites (Uganda, The Gambia, and South Africa) in a laboratory-free manner. Building on extensive experience gained during previous EDCTP-funded projects, the project is based on strong biomarker data, an advanced, user-friendly, rapid, multiplex test device, and implementation expertise supported through EDCTP2.

The project will be implemented in three phases:

1. validation of the existing signature on stored samples from outside Africa
2. refinement/locking of signature
3. large-scale prospective field testing at peripheral health care clinics in Africa

TriageTB is coordinated by Prof Gerhard Walzl from Stellenbosch University (South Africa) and managed by LINQ management GmbH (Germany). The other collaborators are the London School of Hygiene and Tropical Medicine (UK), the Medical Research Council Unit The Gambia at LSHTM (The Gambia), Makerere University (Uganda), Leiden University Medical Center (The Netherlands), and the Foundation for Innovative New Diagnostics (Switzerland).

Duration

48 months (01/10/2019 - 30/09/2023)

Project funding

3,291,740 EUR

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Partners

- London School of Hygiene and Tropical Medicine, UK
- Medical Research Council Unit The Gambia at LSHTM, The Gambia
- Makerere University, Uganda
- LINQ management GmbH, Germany
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