

TB-CAPT

Close the gap, increase access, provide adequate therapy



Acronym

TB-CAPT

Full title

Close the gap, increase access, provide adequate therapy

Programme

The Second European & Developing Countries Clinical Trials Partnership Programme (EDCTP2)

Contract number

Grant Agreement N° RIA2017S-2007

ABSTRACT

Every year, millions of TB infections go unidentified, preventing patients from accessing treatment and allowing the disease to spread. There is an urgent need for TB tools and diagnostic technologies that can not only detect disease but can also identify strains that are resistant to the TB medications that are available. In addition, people living with HIV (PLHIV) are not well served by the current standard sputum-based diagnostics. Non-traditional specimen-types (such as urine, oral swabs and stool) however have shown promise to improve diagnosis in this population and need to be assessed further. Next generation tests need to be placed at the point-of-care at microscopy centre level, fully integrated into the diagnostic and treatment network, connectivity enabled, more sensitive, and able to perform expanded drug susceptibility testing (DST).

TB-CAPT includes a series of clinical trials in Tanzania, Mozambique, and South Africa that will evaluate the impact of novel diagnostic interventions on outcomes, including the effects of expanding TB testing strategies to those who are HIV positive. The trials take local epidemiology and existing infrastructure into consideration and will compare new strategies with current standards of care.

Three activity-areas serve to help TB-CAPT achieve its overarching goals:

- 1. To evaluate the most promising new technologies in settings of intended use, the following key TB diagnostic trials will be implemented in TB-CAPT:**
 - A pragmatic, randomized, controlled trial (→ our CORE trial) that assesses the impact of implementation of the GeneXpert Omni instrument with the Xpert MTB/RIF Ultra cartridge in the most peripheral levels of the healthcare system (such as primary care clinics)
 - Enabling of culture-free diagnosis for drug sensitive and drug resistant TB through implementation of the XDR cartridge (→ our XDR trial), and assess impact
 - Assess expanded testing strategies for the most vulnerable patients with HIV infection (→ our HIV trial) through testing unselected hospitalized PLHIV with Ultra on multiple available samples (sputum, urine, stool) and and FujiLAM on urine.
- 2. Facilitate policy change and inform implementation strategies at global, national, and regional level:** TB-CAPT will inform WHO recommendations on the implementation of the first diagnostic platform suitable to replace smear-microscopy at the most peripheral level of healthcare. Within our trial countries Mozambique, South Africa, and Tanzania, we will work with national programmes, governments, and local implementers to generate data to support the development and execution of implementation plans. In addition, FIND and the African Society for Laboratory Medicine (ASLM) will assist in translating findings to aid scale-up also

beyond trial countries. To achieve this, TB-CAPT will specifically:

- Join forces with other global trial sites to ensure global representativeness of the combined data
- Use transmission and socio-economic modelling to provide the health care system with predictions of impact and cost of implementation on population level
- Ensure early and ongoing engagement with national TB programmes in early adopter countries, with ASLM and the WHO

3. **Strengthen in-country infrastructure and human capacity:** TB-CAPT will work with renowned institutions in our trial countries (Mozambique, South Africa, and Tanzania), local researchers, and government infrastructure, to develop enhanced capacity for conducting clinical trials, implementation research and implementation plans for new diagnostics.

Specifically, we will

- Build capacity within our partner institutions for a series of implementation trials of novel diagnostic tests to follow the TB-CAPT project
- Develop capacity to diagnose and treat DR-TB at level 1 settings

Duration

42 months (01/09/2019 - 28/02/2023)

Project funding

5,975,984 EUR

Coordinator

FIND, the global alliance for diagnostics

Partners

- Foundation for Innovative New Diagnostics (FIND), Switzerland
- Ospedale San Raffaele (OSR), Italy
- University of Cape Town (UCT), South Africa
- Swiss Tropical and Public Health Institute (Swiss TPH), Switzerland
- Ludwig-Maximilians-Universitaet Muenchen (LMU), Germany
- Ifakara Health Institute Trust (IHI), Tanzania
- National Institute for Medical Research - Tanzania (NIMR), Tanzania
- Instituto Nacional de Saúde (INS), Mozambique
- Fundación Privada Instituto de Salud Global Barcelona (ISGlobal), Spain
- Centro de Investigacao em Saude de Manhica (CISM), Mozambique
- Wits Health Consortium (Pty) Ltd (WHC), South Africa
- African Society for Laboratory Medicine (ASLM), Ethiopia
- Heidelberg University Hospital (UKHD), Germany
- LINQ management GmbH (LINQ), Germany

Project management

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