



EDCTP



New support tools for TB vaccine R&D published

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The Tuberculosis Vaccine Initiative (TBVI) has coordinated the development of several new tools to support future TB vaccine clinical trials. Experts in the field together with researchers from the ongoing EDCTP-funded TB vaccine projects developed templates and guidelines. These are to support preparations for a regulatory plan, a data management plan and clinical trial protocol synopses. Furthermore, a comprehensive registry of trial sites in sub-Saharan Africa with capacities to conduct TB vaccine studies has been made available online. EDCTP supported TBVI with an investment of €130,000.

“We are fully committed to highly collaborative research & development (R&D), open science and creating an enabling environment for research that is consistent with international standards and respecting good practices. Our partnership with TBVI on TB vaccines R&D demonstrates our strong commitment to international collaboration that promotes the exchange of knowledge and expertise between researchers, institutions, and partner organisations in Europe, Africa and globally. These valuable TB vaccines R&D tools are of greater utility beyond TB”

Dr Michael Makanga, EDCTP Executive Director

Vaccine development is a complex and long-term endeavour that requires many kinds of expertise and the management of activities running in parallel. Several tools are already available:

- The [TB Vaccine Development Pathway](#) offers a methodology that assists in the management of large, long and complex projects. It has been developed by TBVI and IAVI and other experts on behalf of the Global TB Vaccine Partnership which is funded by the Bill & Melinda Gates Foundation.
- The recently launched [Global roadmap for research and development of tuberculosis vaccines](#) provides a shared set of priorities to guide the activities of all stakeholders with an interest in TB vaccine development and use. The Roadmap has been developed by the Amsterdam Institute for Global Health and Development with support from EDCTP and in collaboration with WHO.

“TBVI works closely with EDCTP to accelerate the most promising TB vaccine candidates through the pipeline. In this project we have worked together with EDCTP-funded projects and experts to develop tools that enable vaccine developers to better manage their vaccine development process, as well as a searchable directory of clinical trial sites in sub-Saharan Africa. TBVI and EDCTP are also working together to facilitate dialogue and exchange of good practices across EDCTP-funded TB vaccine clinical trials”

Nick Drager, TBVI Executive Director

In 2019, EDCTP initiated a project to enhance the coordination and collaboration between the EDCTP-funded TB vaccine research projects. The implementation was entrusted to TBVI. As part of the project, a set of online open-access guidance documents have been developed.

Drafting a regulatory plan for TB vaccine development

The regulatory plan provides guidance when drafting a regulatory plan for a TB vaccine candidate. It includes directions on how to draft the plan and provides considerations and information about the approval process of a TB vaccine.

Preparing a data management plan

A data management plan is a central document to clearly present all key activities that ensure high-quality data management throughout the course of the vaccine development pathway. The guidance documents for such a data management plan include recommendations. The template offers practical support for developing the plan. This template is not unique to TB vaccine research and will be of use to anyone working with clinical study data.

Preparing a clinical trial protocol for different target groups

Three specific templates for different target groups were developed:

1. For studies on preventing TB in neonates of infants;
2. For studies on preventing active pulmonary TB disease in the adolescent/adult population;
3. To be used if the vaccine candidate is intended to treat or cure TB in a TB-infected population either as an adjunct to chemotherapy during or after the TB drugs or as a treatment to prevent relapse.

Clinical trial sites directory

In collaboration with Sub-Saharan clinical research sites, an online directory has been developed to provide a comprehensive overview of clinical trial sites in Sub-Saharan Africa including their capacity to conduct trials on TB vaccines. This directory is accompanied by a data dictionary.

[All tools are available on the EDCTP website.](#)

About EDCTP



E D C T P

The [European & Developing Countries Clinical Trials Partnership \(EDCTP\)](#) is a public–public partnership between 14 European and 16 African countries, supported by the European Union.

EDCTP’s vision is to reduce the individual, social and economic burden of poverty-related infectious diseases affecting sub-Saharan Africa.

EDCTP’s mission is to accelerate the development of new or improved medicinal products for the identification, treatment and prevention of infectious diseases, including emerging and re-emerging diseases, through pre- and post-registration clinical studies, with emphasis on phase II and III clinical trials. Our approach integrates conduct of research with development of African clinical research capacity and networking.

About TBVI



The [Tuberculosis Vaccine Initiative \(TBVI\)](#) aims to support, integrate, translate, and prioritise R&D efforts to discover and develop new TB vaccines that are accessible and affordable for all. In an effort to optimise the discovery and development of new TB vaccines and biomarkers, TBVI facilitates and supports the generation of new knowledge and exchange among R&D partners. TBVI creates an enabling environment for

consortium members to promote knowledge sharing through scientific meetings and workshops, publication in scientific and non-scientific journals, formal and informal networking.