

[Home](#) / [Press Releases](#) / [IAVI and Zendal announce funding for efficacy trial of promising TB vaccine candidate in Africa](#)

December 18, 2023

IAVI and Zendal announce funding for efficacy trial of promising TB vaccine candidate in Africa

ZENDAL



TB kills 1.3 million people a year and sickens more than 10 million people annually.

A new TB vaccine is needed to reach the global End TB goals.

MTBVAC is a highly promising vaccine candidate that has the potential to be used as an alternative to BCG vaccination in infants and for prevention of TB disease in adolescents and adults.

Grant from the Bill & Melinda Gates Foundation to IAVI will support efficacy trial.

NEW YORK, U.S. and PORRIÑO, SPAIN — December 18, 2023 — IAVI, a global nonprofit scientific research organization, and Spanish biopharmaceutical company Biofabri, a subsidiary of Zendal, today announced that the Bill & Melinda Gates Foundation has awarded IAVI US\$55 million to conduct a Phase IIb trial assessing the safety and efficacy of the tuberculosis (TB) vaccine candidate MTBVAC to prevent active TB lung disease in adolescents and adults. This funding has been made possible in part through a grant provided by Open Philanthropy, a grant-making



Kabelo Mabeleng prepares Duglas Netshidzivhani for a vaccine trial at the

organization that aims to use its resources to help others as much as it can. This trial is also supported by additional funding provided by the German Federal Ministry of

Aurum Institute Rustenberg, South Africa. Credit: Mwangi Kirubi

Education and Research (BMBF) through the KfW Development Bank, which provides [funding to IAVI and partners](#) in support of developing MTBVAC. It is anticipated that the trial will begin enrolling participants in mid-2024.

“We’re thrilled to have secured the investment needed to advance this promising vaccine candidate into an efficacy study,” said Mark Feinberg, M.D., Ph.D., president and CEO of IAVI. “The world urgently needs a new, effective vaccine that can prevent TB disease in adults and adolescents, and we are hopeful that MTBVAC will be part of the solution to finally end the TB epidemic. We are grateful to the Bill & Melinda Gates Foundation for their support of our late-stage development work on MTBVAC and to Open Philanthropy, whose visionary investment could accelerate the availability of MTBVAC by several years, if it is shown to be safe and efficacious in the upcoming efficacy trial.”

“This is a historic opportunity to learn whether this promising TB vaccine candidate, MTBVAC, can prevent active TB disease in adolescents and adults, the population among whom most TB disease and transmission occurs,” said Lewis Schrager, M.D., senior leader of TB vaccine development efforts at IAVI. “If MTBVAC were shown to safely prevent TB disease in this population, this vaccine could prove to be critically important in global strategies to suppress the TB pandemic given its ease of use, low cost, and anticipated widespread availability.”

Previous Phase Ib/IIa dose-ranging studies of MTBVAC in adults and neonates demonstrated favorable immunogenicity and safety profiles. In addition to this Phase IIb trial, Biofabri is conducting a Phase III trial of MTBVAC ([NCT04975178](#)) in neonates in South Africa, Madagascar, and Senegal, with support from the European & Developing Countries Clinical Trials Partnership (EDCTP). Biofabri and the HIV Vaccine Trials Network are planning a Phase IIa trial ([NCT0547890](#)) evaluating the safety and immunogenicity of MTBVAC in people living with HIV whose viral loads are well controlled on antiretroviral therapy, scheduled to begin in South Africa in mid-January 2024.

Only a handful of TB vaccine candidate efficacy trials have ever been conducted. This study of MTBVAC to prevent TB disease will be conducted in approximately 4,300 people who have latent TB infection. Participants will be between the ages of 14 and 45, living in South Africa and select other sub-Saharan African countries in areas with high TB burden. Participants at 15-20 trial sites will receive either a single dose of MTBVAC or placebo and be observed for two to three years.

Kundai Chinyenze, M.D., MPH, IAVI Africa director, said, "We are gratified to be able to begin working on this efficacy trial in a region of the world where TB is a leading contributor to morbidity and mortality, especially for people living with HIV. IAVI's long history in conducting clinical trials in Africa and our strong network of regional and global partners provide a solid foundation for the successful conduct of this important trial."

MTBVAC, designed by the Spanish researcher Carlos Martin, Ph.D., from the University of Zaragoza, and Brigitte Gicquel, Ph.D., of Institut Pasteur, was in-licensed by Biofabri (Zendal Group). The only available TB vaccine, bacille Calmette-Guérin (BCG), is derived from *Mycobacterium bovis*, a bacterium that causes a TB-like disease in cows. BCG is largely ineffective in preventing TB in adolescents and adults. MTBVAC is the only live, attenuated vaccine derived from *Mycobacterium tuberculosis*, the bacterium that causes TB disease in humans, in the pipeline. Given its derivation from the human, rather than the bovine, TB-causing organism, MTBVAC has the potential to generate a broad protective immune response against TB. The vaccine is administered as a single dose via intradermal delivery and does not require the use of an adjuvant.

Esteban Rodriguez, CEO, Biofabri, said, "We are delighted by the fantastic opportunity — through the tremendous efforts of IAVI, and the valuable support provided by the Bill & Melinda Gates Foundation, Open Philanthropy, and the German Federal Ministry of Education and Research (BMBF) through the KfW Development Bank — to now evaluate the efficacy of MTBVAC in adolescents and adults. The outcome of the efficacy studies in neonates as well as those in adolescents and adults will provide us with a pathway to license MTBVAC for all age groups."

Should MTBVAC be shown to be safe and efficacious, Biofabri, in partnership with IAVI and other collaborators, will ensure that MTBVAC is manufactured and supplied in sufficient quantities globally and is accessible at affordable prices in low- and middle-income countries.

TB

Since the COVID-19 emergency has ended, TB is on track once again to be the deadliest infectious disease in the world. TB killed an estimated [1.3 million people in 2022](#), about 16% of whom were children. Around [10.6 million people](#) fell ill with TB in 2022, and the disease is one of the 10 leading causes of death worldwide.

Drug-resistant/multi-drug resistant TB (DR/MDR TB) is becoming an increasing threat, with about [410,000 cases in 2022](#). Treating DR/MDR TB is lengthy and expensive, often causes debilitating side effects, and is not always successful. A vaccine that prevents TB disease would play an important role in reducing the incidence of DR/MDR TB, by reducing the transmission of DR/MDR TB and reducing the use of TB drugs and the emergence of drug-resistant strains.

MTBVAC

MTBVAC is being developed for two purposes: as a more effective and potentially longer-lasting vaccine than BCG for newborns, and for the prevention of TB disease in adults and adolescents, for whom there is currently no effective vaccine.

Two Phase II trials have been completed, one [supported by EDCTP](#) and sponsored by Biofabri in infants in South Africa, and one [sponsored by IAVI](#) and supported by the U.S. National Institutes of Health and the U.S. Department of Defense through its Congressionally Directed Medical Research Program. Results are expected to be published in early 2024.

IAVI. IAVI is a nonprofit scientific research organization with headquarters in the U.S. and locations in Europe, Africa, and India that develops vaccines and antibodies for HIV, tuberculosis, emerging infectious diseases (including COVID-19), and neglected diseases, with the goal of providing global access. It has contributed to efforts to evaluate most of the leading TB vaccine candidates now in clinical development and has a highly experienced TB vaccine clinical research team in South Africa.

Biofabri. Biofabri is a biopharmaceutical company created in 2008 with the aim of researching, developing, and manufacturing vaccines for humans. Biofabri has a solid technical and scientific capacity in vaccines and immunotherapy. Biofabri belongs to the Zendal group, a Spanish pharmaceutical business group made up of six companies specialised in the development, manufacture and marketing of vaccines and other biotechnological products for human and animal health.

UNIZAR. The University of Zaragoza in Spain is the main center for technological innovation in the Ebro Valley. It participates in different exchange programs, collaborating with universities and research centers in Europe, Latin America, and the United States. Microbiologists from the university associated with Centro de Investigación Biomédica en Red Enfermedades Respiratorias (CIBERES) led the research and subsequent discovery of the experimental vaccine MTBVAC. Within the TuBerculosis Vaccine Initiative (TBVI) consortium, the MTBVAC discovery phase has included rigorous clinical characterization by independent laboratories and research groups.

IAVI Media Contact

Karie Youngdahl

+1 212 847 1051

kyoungdahl@iavi.org

Zendal Media Contact

Beatriz Díaz Lorenzo

+34 619 085 074

b.diaz@zendal.com

The state of vaccine science now is far more powerful and sophisticated than it has ever been. And I am confident that many of these challenges that we face will be solved by vaccine development.

Mark Feinberg
President & CEO



[MENU](#) 

We are a nonprofit scientific research organization that develops vaccines and antibodies for HIV, tuberculosis, and emerging infectious diseases.



Quick Links

- [Careers](#)
- [HIV Vaccines](#)
- [HIV Antibodies](#)
- [Tuberculosis](#)

Contact Us

IAVI U.S.
125 Broad Street, 9th Floor
New York, NY 10004

Emerging Infectious Diseases

USAT: +1.212.847.1111

F: +1.212.847.1112



[Contact us](#)

[Diversity, Equity, & Inclusion](#)

[Privacy Policy](#)

[Terms of Use](#)

[Compliance](#)

[& RFPs](#)

©2024 International AIDS Vaccine Initiative. International AIDS Vaccine Initiative®, IAVI®, and the IAVI

Subscribe