MTBVAC

The only live-attenuated M.tb vaccine in development

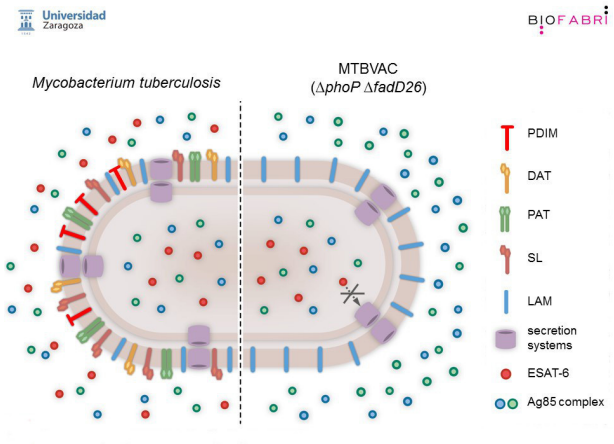
Translating **science** into **global** health impact

The only available tuberculosis (TB) vaccine is the century-old Bacille Calmette Guérin (BCG). While BCG offers important but incomplete protection against the most severe forms of TB, such as TB meningitis, in infants and young children, it is mostly ineffective in adolescents and adults, who are most at risk of developing and spreading TB. Almost 90% of TB cases occur among adolescents and adults.

Multiple new TB vaccines that work across all age groups, particularly among adults and adolescents, will be critical to eliminate TB by 2030 and meet the World Health Organization's End TB targets.

MTBVAC at-a-glance

- MTBVAC is derived from human M.tb, not bovine tuberculosis (as in BCG) and uses a weakened, harmless form of the pathogen to stimulate an immune response.
- It contains the full complement of antigenic targets of the original pathogen (meaning the full range of targets on the pathogen that may be involved in generating an immune response against TB).
- Preclinical data comparing MTBVAC to BCG shows MTBVAC is as safe as BCG while being more immunogenic and protective.



A Spanish vaccine for the world

25 years of research and development of MTBVAC

MTBVAC was designed and constructed by Professor Carlos Martin from the University of Zaragoza, Spain, in collaboration with the Institute Pasteur, and later in-licensed by the Spanish biotechnological company Biofabri, Zendal Group.

Over the last 25 years, MTBVAC has been tested in a range of preclinical animal model studies in mice, guinea pigs, and macaques.

In humans, four clinical trials have been completed in infants, adolescents, and adults since 2013, leveraging the expertise of a global network of partners. These earlier-stage dose-ranging studies of MTBVAC in adults and infants have demonstrated favorable immunogenicity and safety profiles.

An access-informed value proposition for MTBVAC

If MTBVAC is shown to safely prevent TB disease, it could be critically important in global efforts to suppress the TB pandemic given its ease of use, low cost, and anticipated widespread availability.

Broad antigen presentation
Only vaccine directly derived from M.tb isolate in humans, presenting a broad range of antigens

Ease of administration
Single dose delivery to support uptake

Non-adjuvanted formulation
No supply/price dependence from additional commercial partners

Commitment to affordability
Vaccine platform with relatively low cost-of-goods and established commitment to affordable pricing from commercial partners

Global manufacturing footprint
Manufacturing partners lined up in Europe, India, and South America, increasing global supply capacity, supply security, and regional equity

MTBVAC late-stage development status

Phase 2-3 trials for prevention of disease

Phase 1b/2a in adults

Completed [NCT02933281]

- Safety/immunogenicity/dose-finding study
- 144 HIV-negative adults in South Africa with and without previous TB infection
- Trial sponsor: IAVI

Phase 2a in people living with HIV

Ongoing [NCT05947890]

- Safety/immunogenicity study
- Adolescents and adults in South Africa
- Trial sponsor: HVTN

Phase 2b in adolescents and adults

Planned [NCT0627281]

- ~4,300 HIV-negative participants with latent TB
- Trial sponsor: IAVI
- Anticipated study start: Q3/4 2024

Phase 3 in infants

Ongoing [NCT04975178]

- ~7,000 infants in South Africa, Senegal, and Madagascar with BCG control arm
- Trial sponsor: Biofabri

Opportunities to accelerate MTBVAC toward licensure and global equitable access

Expansion of MTBVAC efficacy testing [Phase 2b] to include a cohort of **people living with HIV**

Expansion of MTBVAC efficacy testing [Phase 2b] to include a cohort of **people without TB infection** [IGRA-negative]

Develop regulatory & access plans to enable the rapid deployment of MTBVAC (if results of efficacy testing justify licensure)

Expansion of MTBVAC efficacy testing to **additional geographic settings**, i.e., Southeast Asia, Latin America

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