

# MTBVAC



Translating science  
into global health impact

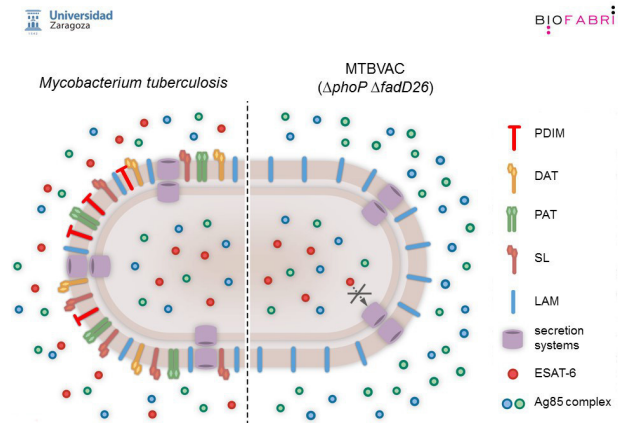
## The only live-attenuated Mtb vaccine in development

The only available 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 WHO End TB targets.

### MTBVAC at-a-glance

- MTBVAC is derived from human Mtb, 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, Zental 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 Mtb 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 & adults

Planned [[NCT0627281](#)]

- ~4,300 HIV negative participants with latent TB
- Trial sponsor: IAVI
- Anticipated study start: Q1 2025

#### 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 towards 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

IAVI gratefully acknowledges the generous support provided by the following major funders:



Biomedical Advanced Research and Development Authority (BARDA) | Foundation for the National Institutes of Health | National Institute of Allergy and Infectious Diseases | amfAR, The Foundation for AIDS Research | Broadway Cares/Equity Fights AIDS | The City of New York, Economic Development Corporation | Congressionally Directed Medical Research Program (DoD) | GSK | The Hearst Foundations | Keith Haring Foundation | Merck & Co., Inc., Kenilworth, NJ, USA (known as MSD outside the USA and Canada)

And many other generous individuals and partners around the world

As of January 2024



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