

Frequently Asked Questions: M72/AS01E Manufacturing

1 Is TB still a public health problem?

Tuberculosis (TB) is the leading infectious cause of death worldwide. An estimated [10.7 million people developed active TB](#) in 2024 and [1.23 million lost their lives](#) – more than 3,300 people per day.

TB disproportionately affects people in low- and middle-income countries, with those at highest risk often living in poverty and facing undernutrition and poor living and working conditions. The economic burden of living with TB is also severe, with [nearly half of TB-affected households experiencing costs exceeding 20% of their annual income](#), often pushing already vulnerable families deeper into poverty.

Innovative solutions to stop TB are urgently needed, including new TB vaccines that can help protect adolescents and adults from the disease.

2 Why is a new TB vaccine needed?

The only available TB vaccine, [BCG](#), can help protect infants and young children against certain severe forms of TB, but it offers limited protection against pulmonary TB, the most common form of the disease and primary driver of transmission, particularly in adolescents and adults. A robust [pipeline](#) of novel vaccine candidates is under development to address this gap.

The World Health Organization [estimates](#) that over a 25-year time span, a TB vaccine offering approximately 50% protection against progression to active pulmonary TB could save 8.5 million lives, prevent 76 million new TB cases, and save \$41.5 billion for TB-affected households.

3 What is M72/AS01E, and how does it work?

M72/AS01E is a TB vaccine candidate currently being studied in a Phase 3 clinical trial, and if successful, could be the first novel TB vaccine to be introduced in over a century, and the first-ever specifically for adolescents and adults.

The M72/AS01E vaccine is made of two components: the antigen (M72), which helps the body's immune system to recognize and fight the *Mycobacterium tuberculosis* bacteria and the adjuvant (AS01E), which is designed to boost and broaden the immune response. TB is a complex disease that can lie dormant in the body for years, or even indefinitely ('latent' TB). A person becomes ill – and able to transmit the disease – if the infection progresses from 'latent' to 'active' TB. The M72/AS01E vaccine candidate aims to prevent that progression to active TB.

4 What is the status of M72/AS01E's clinical development?

M72/AS01E has been in development since the early 2000s. It was originally developed and clinically evaluated by GSK through the Phase 2b stage, in partnership with Aeras and the International AIDS Vaccine Initiative (IAVI), with funding from GSK and the Gates Foundation.

In 2020, GSK partnered with the Gates Medical Research Institute (Gates MRI) to advance the vaccine into late-stage development. Gates MRI is now sponsoring the ongoing Phase 3 clinical trial, with funding support from the Gates Foundation and Wellcome. GSK continues to supply the AS01E adjuvant for the vaccine.

The Phase 3 trial was initiated in March 2024 across 54 sites in Indonesia, Kenya, Malawi, South Africa, and Zambia and reached full enrollment of 20,000 adolescents and adults aged 15–44, including people living with HIV.

Participants have received either the investigational M72/AS01E vaccine or a placebo in a double-blind study, meaning neither participants nor investigators know who received the vaccine. Participants will be evaluated for up to four years to determine whether the vaccine helps prevent progression to active TB disease.

5 Is M72/AS01E safe and effective?

Before the current Phase 3 clinical trial, M72/AS01E was evaluated in multiple Phase 1 and 2 studies and demonstrated a clinically acceptable safety profile across studied populations.

In a Phase 2b trial, the vaccine candidate [showed](#) approximately 50% protection against progression to active pulmonary TB over a three-year follow-up period in *Mycobacterium tuberculosis*-infected, HIV-negative adults aged 18 to 50 years.

Additional studies in people living with HIV [showed](#) that the vaccine was well tolerated and generated an immune response in this population.

6 How were countries selected to participate in the Phase 3 trial?

The Phase 3 trial site countries – Indonesia, Kenya, Malawi, South Africa, and Zambia – were selected based on a combination of scientific, epidemiological, and operational factors, as well as alignment with national priorities. The countries bring strong experience in global TB and vaccine clinical research, supporting high-quality data generation and rigorous protection of participant safety.

7 How are local communities involved in the M72/AS01E clinical trial?

Community engagement is an important part of how clinical trials are conducted, particularly in high-burden settings. Trial sites work closely with local communities to ensure that participants are informed, respected, and supported throughout the study. This includes engagement with community representatives – such as Community Advisory Boards in some settings – as well as clear communication about the purpose of the research, the informed consent process, and participants' rights.

All study activities are conducted in line with local and international ethical and regulatory standards, with oversight from ethics committees to help ensure the safety, dignity, and well-being of participants.

8 Who will manufacture M72/AS01E, if approved?

Gates MRI has signed an agreement with the Serum Institute of India (SII) to manufacture M72/AS01E. SII was selected based on several key criteria. We looked for a global manufacturing partner with a strong track record of producing-WHO prequalified vaccines, affordably and at scale, and meeting stringent global regulatory and manufacturing standards.

Under the agreement, SII will manufacture the M72 antigen component of the vaccine, while the AS01E adjuvant is supplied by GSK under a separate agreement between GSK and SII. Partners are actively engaged in demand forecasting and supply planning to help ensure both components can be available in a coordinated and timely manner, should the vaccine be approved.

Importantly, SII shares the M72 partners' commitment to global access and to engaging local manufacturers in Indonesia and South Africa to support critical parts of the supply chain over time. Indonesia and South Africa were identified as important partners given the leading role they play in manufacturing and supply for their respective regions, as well as their participation in the M72/AS01E Phase 3 trial. Partnership across regions heavily affected by TB is part of our broader effort to help build more sustainable and geographically diverse vaccine supply chains over time.

9 Why did Gates MRI select a manufacturer now, before Phase 3 results are known?

Establishing manufacturing capabilities early is a deliberate step to reduce the time between potential clinical success and real-world access. Technology transfer is complex and time intensive. Starting this process now helps ensure that, if the vaccine is successful and approved, doses can be produced and made available to countries with a high TB burden as quickly as possible.

10 When could the vaccine become available?

Results of the trial are anticipated in late 2028 with global and local regulatory submissions starting in 2029, if the vaccine is proven to be well tolerated and efficacious.

11 If approved, will the vaccine be affordable for low- and middle-income countries?

Making M72/AS01E accessible, available, and affordable for countries with a high TB disease burden is a shared priority across all partners. We are actively working with multilateral, regional, and country partners to understand potential demand and build an end-to-end plan to ensure long-term sustainable access to the vaccine in low- and middle-income countries with a high burden of TB, if and once approved.

As with any new global health tool, introduction and scale-up will be a collective effort, requiring coordination and investment from governments, donors, manufacturers, and partners across the global health ecosystem.