

Pipeline Report » 2026

Tuberculosis Vaccines

TAG

Treatment Action Group

Tuberculosis Vaccines

Focusing on what counts

by Mike Frick

Finally, some answers: the past year resolved several longstanding questions in tuberculosis (TB) vaccine research and development (R&D). News came from both the pipeline itself, with the publication of past-due VPM1002 phase III results, as well as the busy terrain of vaccine preparedness, where the marquee event was the selection of a commercial manufacturer for M72/AS01E. Both developments centered on a large company that up until now has operated under the radar in TB vaccine development: Serum Institute of India (**SII**).

Readers would be justified in interpreting “longstanding” in the opening sentence as a euphemism for “delayed.” The biggest stories of the year were ones expected to break years ago, and the wait for information inspired a fair amount of educated guesswork. If one can look past the timing, a good answer is a clear one, and on this score, the resulting picture of the pipeline is less murky than before. Several perennial issues hanging over TB vaccine development have come into sharper focus, clarifying where funders, researchers, policy makers, and advocates should direct their attention in coming years.

On the clinical side, the unwritten final chapter of the VPM1002 vaccine candidate is mostly printed now that two of its **three phase III trials** have published results. The first of those studies to report, in *The BMJ* in April 2026, was funded by the Indian Council of Medical Research (ICMR) and evaluated whether VPM1002 and a second vaccine called MIP (Immuvac) could prevent TB disease among 12,500 household contacts of people with TB. (Each vaccine was evaluated individually against placebo; neither met the primary endpoint.) The second study, sponsored by SII and published in the *Lancet Infectious Diseases* in August, pursued a **BCG**-replacement strategy and assessed the efficacy of VPM1002 in preventing *Mycobacterium tuberculosis* (MTB) infection among infants. (The short answer is BCG is not going anywhere.)

The third phase III trial asks whether vaccination with VPM1002 after treatment reduces the risk of recurrent TB disease. The results of this last study are unpublished at the time of writing but are known to many pipeline watchers in broad strokes. They were presented in at least one closed forum: the January 2025 annual meeting of the TuBerculosis Vaccine Initiative in Les Diablerets, Switzerland (TAG was not present).¹ Topline results were also summarized in the minutes of a Special Expert Committee meeting of India’s Drugs Controller General in October 2025. The minutes leave a lot to interpretation but indicate no statistically significant difference in rates of recurrent TB between the VPM1002

SII, based in Pune, India, is the world’s largest vaccine manufacturer by volumes sold.

Three phase III trials of VPM1002:

- Prevention of disease (POD): [CTRI/2019/01/017026](#)
- Prevention of infection (POI): [NCT04351685](#)
- Prevention of recurrence (POR): [NCT03152903](#)

BCG = Bacille Calmette-Guérin, the only licensed TB vaccine developed in the early twentieth century.

and placebo groups.² Serum Life Science Europe, which licensed VPM1002 to SII in 2013, shared with TAG that the results manuscript is “under preparation” and will be submitted for publication pending additional statistical analyses.³

Two negative phase III clinical trials in one year (or three, if one counts the prevention-of-recurrence study) is a large setback by any measure, but it was not all bad news for SII. On the vaccine preparedness front, the Gates Medical Research Institute (Gates MRI) named SII as the commercial manufacturer of M72/AS01E.⁴ If not exactly a surprise given SII’s formidable abilities, the choice settled a question that has chased M72/AS01E ever since the conclusion of its **phase IIb trial** in 2018. Despite observing a positive efficacy signal in that study, GSK elected not to take the candidate forward on its own (a story covered by ProPublica and in previous *Pipeline Reports*).^{5,6} Followers of TB vaccine science had known a manufacturer for M72/AS01E would be appointed ever since January 2020 when the Gates MRI took over rights to develop the vaccine from GSK. That licensing agreement said that the Gates MRI would “lead vaccine candidate development and sponsor future clinical trials,”⁷ with GSK providing the adjuvant — but it did not specify an ultimate marketing authorization holder responsible for making, selling, and distributing the vaccine pending a successful phase III clinical trial and favorable regulatory review. The **M72 Partners** pushed back the timeline for announcing a commercial partner several times before naming SII in July 2026.

Behind these headliner events were many less-observed moves that pulled the pipeline into focus. A quick visual assessment of the pipeline (**Figure 1**) is enough to know that a lot changed over the past year. Several candidates, including three mycobacterial vaccines, have dropped out of the pipeline (see list below). VPM1002 remains listed while the field awaits peer-reviewed publication of results from its **POR** phase III trial, but its pathway forward is uncertain. The reasons candidates exited the pipeline vary:

- Development of MIP has stopped due to negative results from the ICMR-funded phase III trial, discussed in section VPM1002: *Writing Its Final Chapter?*
- The Henry M. Jackson Foundation terminated a phase III trial of **BCG as a travel vaccine** due to “slower-than-anticipated recruitment and limited remaining research funding.”⁸ The trial tested whether vaccination with BCG before travel could prevent MTB infection among United States health care workers and long-term travelers bound for high-TB-burden countries. By its discontinuation in January 2026, the trial had enrolled 16 of 2,000 participants.
- The inactivated, whole-cell mycobacterial vaccine DAR-901 has not registered a new trial since completing a **phase II POI trial** in Tanzanian adolescents in 2020.⁹ The team behind DAR-901 at Dartmouth University is turning over development to the International Vaccine Initiative; the two parties have applied for joint funding, which could return the candidate to the pipeline in coming years.¹⁰

Results of the M72/AS01E **phase IIb trial** (NCT01755598) were published in NEJM.

M72 Partners refers here to the Gates MRI (trial sponsor), the Gates Foundation and Wellcome (funders), GSK (originator and adjuvant holder), and now SII (commercial lead).

POR = prevention of recurrence. POR trials test whether vaccines prevent disease recurrence (usually encompassing both reinfection and relapse).

Phase III trial of **BCG as a travel vaccine** NCT04453293 (terminated early).

Phase II POI trial of DAR-901 NCT02712424.

POI = prevention of infection. POI trials test whether vaccines prevent MTB infection, usually measured by IGRA test conversion (negative to positive).

- Work on viral vector vaccines ChAdOx1 85A + MVA85A, most recently studied in a prime/boost strategy in a **phase IIa trial** in Ugandan adolescents that published results in 2024,¹¹ is transitioning to a related project funded by the **EDCTP** called T5-TBVAC. The project is developing a new viral vector vaccine called ChAdOx1 T5. Designed for aerosol delivery, the vaccine uses the ChAdOx1 chimpanzee adenovirus viral vector platform to deliver **five MTB antigens**.^{12,13} Expect to see ChAdOx1 T5 enter the pipeline in the coming years: the T5-TBVAC project includes plans for a phase I trial in UK adults that will compare high- and low-dose ChAdOx1 T5 administered via aerosol and intramuscular injection, and test preliminary efficacy against an intradermal (skin) BCG challenge. Two phase IIa trials will follow in Uganda and Senegal. The trial in Uganda will test ChAdOx1 T5 in a BCG skin challenge model that will assess the effect of the vaccine on BCG replication.¹⁴

Phase IIa trial of ChAdOx1 85A + MVA85A [NCT03681860](#).

EDCTP = European and Developing Countries Clinical Trials Partnership, a joint undertaking of the European Commission.

The **five MTB antigens** in ChAdOx1 T5 are Ag85A, PPE15, PE8, ESXJ, and ESXI.

That leaves 14 candidates in the pipeline (down from the 17 reported by TAG last year). At least 20 countries have recently hosted, or will soon host, TB vaccine clinical trials, involving over 100,000 participants — making TB vaccine R&D a truly global endeavor. Tables 1 and 2 list each candidate alongside information on ongoing, recently completed, and planned clinical trials registered with health authorities. Regular *Pipeline Report* readers may notice that the tables have been redesigned to standardize and simplify the trial summaries. **Table 1** reviews vaccines that have reached phase II or III trials with efficacy endpoints; candidates in earlier stages of development are in **Table 2**.

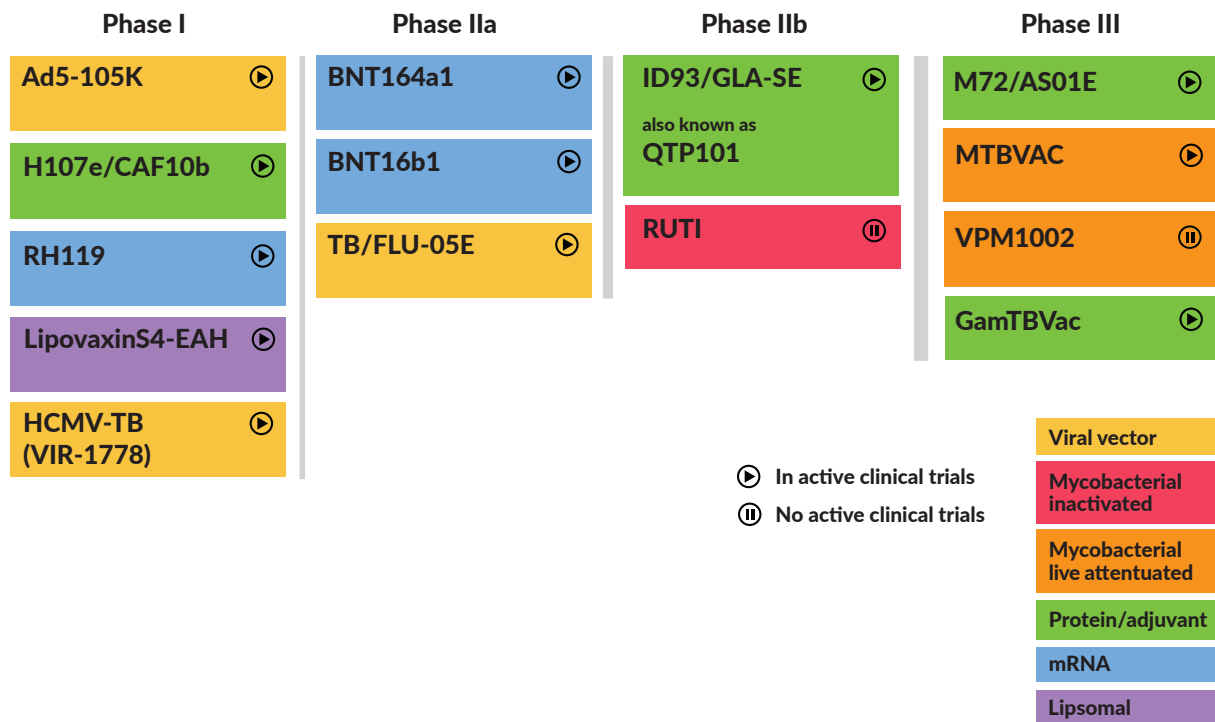
As this report went to press, Anhui Zhifei Longcom informed TAG that it has “no current plans to conduct additional studies with the original AEC/BC02 candidate,” whose phase II trial ([NCT05284812](#)) was suspended since 2023.

The removal of several familiar names emphasizes the pipeline’s thinness in early phases. Two new entrants — LipovaxinS4-EAH and HCMV-TB — add names to three candidates newly listed last year: H107e/CAF10b, Ad5-105k, and RH119. The glass-half-empty view is that an underpopulated early pipeline robs the field of backup options if candidates in late-stage development disappoint. The glass-half-full view recognizes that candidates in phase I, though small in number, add some modest diversity in platform, delivery mechanism, and MTB antigen presentation. The highlight box *Spotlight: New Names in Phase I* summarizes what is known about these new(er) vaccines.

The company said its work on antigen design and adjuvant optimization continues.

With the VPM1002 phase III program all but closed, focus is falling even more heavily on M72/AS01E and a second leading candidate, MTBVAC. Following behind them in phase IIb is ID93/GLA-SE, a subunit vaccine referred to as QTP101 by its primary sponsor, Korean biotech company Quratis. For Quratis and other developers with earlier-stage candidates, the challenge is to define a pathway through late-stage development without yet knowing the outcomes of the M72/AS01E and MTBVAC efficacy trials. Running outside the limelight is the Russian candidate GamTBVac, whose phase III trial underwent an intriguing revision publicized for the first time this year. The narrative vignettes in this year’s *Pipeline Report* summarize major developments for candidate in phase IIb/III trials.

Figure 1: The TB Vaccine Pipeline



Spotlight: New Names in Phase I

Ad5-105k: a viral vector vaccine constructed from replication-deficient human adenovirus serotype 5 with a fusion protein of three MTB antigens (Ag85A, MTB32A, MTB39A). Sponsored by CanSino (China), Ad5-105k is designed to be given by mouth through nebulized inhalation. Ad5-105k is completing its first **phase I trial** in partnership with Indonesian company PT Etana Biotechnologies among 36 **IGRA**-positive adults in Indonesia. Following this, CanSino is considering a phase Ib or seamless phase Ib/II trial of Ad5-105k in adolescents and adults aged 15 and older in China and Indonesia. Ad5-105k is being developed to prevent TB disease, with a focus on people who are IGRA positive in early trials; IGRA-negative persons and PLHIV may be included in later-stage studies.¹⁵

H107e/CAF10b: a subunit vaccine developed by Statens Serum Institut (Denmark) that combines eight MTB antigens with the liposomal CAF10b adjuvant. Statens Serum Institut has completed enrollment in a **phase Ia/Ib trial**. Dose-ranging work in phase Ia tested two intramuscular injections of H107e (unadjuvanted), CAF10b adjuvant, and combined H107e/CAF10b at low- and high-adjuvant doses among 40 IGRA-negative adult volunteers. Data showed an acceptable safety profile and significant induction of T cell and antibody responses.¹⁶ In the phase Ib stage, 100 IGRA-positive and IGRA-negative adults were randomized to one of four arms: H107e/CAF®10b, H107e/CAF®10b + BCG coadministration, BCG, or placebo. Statens Serum Institut is planning two phase I/II dose-finding studies,

Ad5-105k **phase I trial** NCT06732583.

IGRA = interferon-gamma release assay, a blood-based test that detects cell mediated immune responses to MTB indicative of infection, but not a direct measure of infection itself.

Data from the **phase Ia/Ib trial** of H107e/CAF10b (NCT06050356) will be presented at the Global Forum on TB Vaccines in April 2027.

one among IGRA-positive/negative participants and one including people living with HIV (PLHIV).¹⁷ To support these studies, GMP manufacturing has been transferred to EuBiologics (South Korea) with support from the RIGHT Foundation.¹⁸

RH119: a lyophilized mRNA vaccine belonging to **Rhegen Bio** (China), a biotech company with an mRNA platform for oncology, autoimmune disease, and major infectious diseases. RH119 contains three MTB antigens selected to cover different stages of MTB infection: an early secreted antigen, a latency-associated antigen, and a PE/PPE-family antigen.¹⁹ Rhegen Bio obtained clinical trial approval from China's National Medical Products Administration in August 2025 and has registered **two phase I trials**. The first is among 56 IGRA-negative adults in Wuhan, and the second is among 36 IGRA-positive adults in Beijing. Both trials are generating safety and immunogenicity data by evaluating two doses of RH119, spaced one month apart, at three dose levels. Although plans for phase II trials are not yet finalized, the intended indication of RH119 is prevention of disease with a focus on adults with MTB infection.²⁰

LipovaxinS4-EAH: a self-adjuvanting liposomal recombinant protein vaccine developed by Australian company Lipotek in collaboration with **PT Bio Farma**.²¹ PT Bio Farma is conducting a **phase I trial** for safety, immunogenicity, and dose-finding in 60 IGRA-negative adults in Indonesia. The clinical development program has received funding from the Indonesian Ministry of Health, with future phase I/II studies contingent on positive results from this first-in-humans study.²² The primary target indication for the vaccine is prevention of disease in adolescents and adults. Lipotek describes the Lipovaxin technology as an "adjuvanted delivery vehicle for recombinant antigens," which attach to the surface of liposomes and are presented to immune cells.²³ Lipovaxin refers to the core platform technology, S4 is the integrated adjuvant (a TLR4 agonist), and EAH is the recombinant fusion protein (ESAT-6 and Ag85C).

HCMV-TB (VIR-1778): a viral vector vaccine comprised of recombinant cytomegalovirus (rCMV) and based on work by scientists at Oregon Health & Science University. The vaccine uses a weakened form of CMV to deliver seven MTB antigens; an earlier version of this construct generated considerable excitement in a preclinical rhesus macaque challenge study.²⁴ Development of the vaccine sat with Vir Biotechnology (USA), but sponsorship transferred to the Fred Hutchinson Cancer Center (Fred Hutch) when the company dropped its TB work following strategic restructuring.²⁵ In September 2026, as this report went to press, the HIV Vaccine Trials Network (HVTN) at the U.S. National Institutes of Health (NIH) registered a safety, immunogenicity, and dose-finding **phase I trial** of HCMV-TB.²⁶ The trial will enroll 116 adults in Peru and is slated to open in early 2027 (though the uncertain future funding picture of the NIH-supported HIV/AIDS clinical trials networks may affect this).

Rhegen Bio is the English moniker of Chinese company Shenzhen Ruiji Biotechnology (深圳瑞吉生物科技有限公司).

Two phase I trials of RH119 ChiCTR2500109630 and ChiCTR2400094049.

PT Bio Farma is a state-owned Indonesian vaccine manufacturer.

In addition to LipovaxinS4-EAH, in 2019, PT Bio Farma entered an agreement with Quratis for the QTP101 vaccine.

Phase I trial of LipovaxinS4-EAH NCT07647107.

Phase I trial of HCMV-TB NCT07818824.

M72/AS01E: Reaching Clinical and Commercial Milestones

Since the last *Pipeline Report* was published in March 2025, the M72/AS01E phase III program has passed a series of important milestones. The **phase III trial** reached full enrollment in April 2025, 11 months ahead of schedule and just over a year after opening.²⁷ Investigators attributed this feat to the apparent enthusiasm of local communities near trial sites to enroll, and the diligent preparations made before the trial to understand site-level TB epidemiology and rates of **IGRA positivity**.²⁸

The phase III trial is being conducted at 54 sites in **five countries**. A total of 20,080 adolescents and adults have now been randomized to receive two doses of vaccine or placebo. Each participant will have at least 13 months of follow-up; for the primary efficacy analysis, the clock starts one month after the second vaccine dose to allow sufficient time for the vaccine-induced immune response to develop following completion of the two-dose vaccination series.²⁹

Readers interested in the design details of the phase III trial can dig into study protocol, which Gates MRI published in June 2025, and a paper outlining simulations to assess the feasibility of different design choices.^{30,31} The participant population is divided into three cohorts, the largest comprised of 18,000 HIV-negative, IGRA-positive adolescents and adults 15–44 years of age (IGRA-positive cohort). The primary efficacy analysis is powered on this group and will take place after investigators observe 110 events that meet the primary endpoint: laboratory-confirmed pulmonary TB disease that occurs one month after the second vaccine dose in a participant presenting with one or more signs/symptoms of TB and who has at least two positive sputum test results (positive culture and/or Xpert Ultra) from the same or different sputum samples taken before initiation of TB treatment.

Trial simulations indicated that 110 events would provide greater than 90% power to detect a vaccine efficacy of 55%, with the lower bound of the 95% confidence interval exceeding 10%. Based on a sample size of 18,000 in the IGRA-positive cohort, and an assumed TB incidence rate of 0.4% per year among participants in the control group, the simulations showed a 90% probability of accruing 110 events within four years of beginning enrollment.³² The official line from Gates MRI is that: “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.”³³

Two smaller cohorts of 1,000 participants each will contribute safety and immunogenicity data in IGRA-negative individuals and in PLHIV. The IGRA-negative cohort will inform a secondary analysis looking at vaccine efficacy against prevention of **sustained MTB infection**. Another secondary endpoint will assess prevention of TB disease among participants in the IGRA-negative cohort and those in the HIV cohort who enter the trial with a negative IGRA test. An immunogenicity subgroup will include 1,200 participants (400 from each cohort).

M72/AS01E **phase III trial** [NCT06062238](#).

The Gates MRI conducted a large preparatory study assessing **IGRA positivity** at 45 sites in 14 countries (NCT05190146); results were published in April 2026.

Five countries are participating in the M72/AS01E phase III trial: Indonesia, Kenya, Malawi, South Africa, and Zambia.

Sustained MTB infection = an IGRA that converts from negative to positive and remains positive on repeat testing months later.

The idea is that if favorable safety and immunogenicity are demonstrated in these two smaller cohorts, the benefit/risk assessment for the overall population in high-TB-burden countries should be considered positive, and vaccination could potentially be recommended regardless of HIV or IGRA status.³⁴ That is, regulators and policy makers would support the use of M72/AS01E without requiring HIV or IGRA testing prior to vaccination, even though the phase III trial is not powered to demonstrate efficacy in these groups.

With the trial running fully enrolled, attention has shifted to the commercial side, where the announcement of SII as the manufacturer of M72/AS01E settled a longstanding question — and raised some new ones. The agreement between the Gates MRI and SII has not been published, and a “frequently asked questions” document issued alongside the press release hewed close to rudimentary questions (e.g., “Is TB a public health problem?”) without saying much about the arrangement itself.

Here’s what is known: SII will manufacture the M72 antigen with the AS01 adjuvant “supplied by GSK under a separate agreement between GSK and SII.”³⁵ With the agreement signed, the Gates MRI and SII have initiated technology transfer to share the knowledge and know-how required to make the M72 antigen and enable future large-scale production. SII was selected for its strong track record of producing WHO-prequalified vaccines affordably, at scale, and up to stringent global quality and regulatory standards. The company expects to invest up to \$100 million of its own resources to strengthen manufacturing readiness.³⁶

A notable aspect of the Gates MRI-SII deal is the work SII will do with local manufacturing partners in Indonesia and South Africa “to support critical parts of the supply chain over time.”³⁷ The vision, though not stated directly in the press materials, is for manufacturers in Indonesia and South Africa to act as local marketing authorization holders from day one, responsible for activities like labeling, packaging, and distribution. These partners may gradually assume more manufacturing responsibilities, requiring SII to manage its own series of technology transfers. This localization is an admirable aspect of the Gates MRI-SII partnership and is a step toward greater **vaccine sovereignty** in the Global South.

Here’s what is not clear: The Gates MRI-SII announcement did not specify a list of territories in which SII has rights to sell the vaccine. It did not say much about vaccine price beyond general statements of commitment to making M72/AS01E available and affordable to high-TB-burden countries. It did not name the local manufacturing partners in Indonesia and South Africa, put timelines behind identifying them, or describe their level of involvement in manufacturing or degree of independence from SII. It did not quantify volumes of antigen and adjuvant that will be made available at launch. It did not describe other important elements of the agreement such as audit, compliance, and safeguards to ensure this vaccine, whose development has relied on philanthropic and public funding, will be treated as a global public good should its phase III trial meet with success.

Vaccine sovereignty refers to countries having more control over vaccine manufacturing and supply chains and is variably framed as a matter of justice, industrial policy, or global health security.

Table 1: TB Vaccine Candidates in Trials with Efficacy Endpoints

Vaccine Candidate	Vaccine Type	Sponsor(s) and Major Partners	Status ^a	
Trial phase Registry no.	Trial description and endpoints	Study population	Timeline	Countries
M72/AS01E	Protein/adjuvant subunit vaccine	Gates MRI, Gates Foundation, Wellcome, GSK (AS01E adjuvant), SII	Phase III	
Phase III NCT06062238 	Efficacy, safety, and immunogenicity of M72/AS01E vs. placebo POD	20,080 adults aged 15–44 years - IGRA+ cohort: 18,000 - IGRA- cohort: 1,000 - PLHIV cohort: 1,000 IGRA+/- adults living with HIV	Start: Mar. 2024 Completion: ^b Apr. 2028	Indonesia, Kenya, Malawi, South Africa, Zambia
Phase II NCT04556981 	Safety and immunogenicity of M72/AS01E vs. placebo	402 adults living with HIV (on ART, previous TPT) aged 16–35 years	Start: Nov. 2020 Completion: Aug. 2022 Results: Lancet HIV	South Africa
MTBVAC	Live, genetically attenuated MTB	Biofabri, Bharat Biotech, IAVI, U.S. NIH, FAP, U. Zaragoza	Phase III	
Phase III NCT04975178 MTBVACN3	Efficacy, safety, and immunogenicity of MTBVAC vs. BCG POD	7,120 HIV-exposed and unexposed infants aged 0–7 days	Start: Oct. 2022 Completion: Feb. 2029	Madagascar, Senegal, South Africa
Phase IIb NCT06272812 IMAGINE	Efficacy, safety, and immunogenicity of MTBVAC vs. placebo POD	5,500 adolescents and adults aged 14–45 years - IGRA+ cohort: 4,300 - IGRA- cohort: 1,200	Start: Feb. 2025 Completion: Jun. 2028	Kenya, South Africa, Tanzania
Phase II NCT05947890 HVTN605/A5421 	Safety and immunogenicity of MTBVAC vs. BCG	279 IGRA+/- adults aged 12–55 years - Cohort 1: 84 HIV-negative - Cohort 2: 108 PLHIV with CD4 ≥200 cells/mm³ before ART initiation - Cohort 3: 84 HIV-positive with CD4 >100 cells/mm³ before ART (re) initiation	Start: Jan. 2024 Completion: Jun. 2027	South Africa
Studies of MTBVAC (BBV169) sponsored by Bharat Biotech				
Phase III Not yet registered	Efficacy, safety, and immunogenicity of MTBVAC vs. placebo POD	>25,000 IGRA+/- adolescents and adults aged 12–65 years	Start: late 2026 Completion: 2031	India
Phase II NCT06997367	Safety and immunogenicity of MTBVAC vs. BCG	164 IGRA+/- adolescents and adults aged 12–65 years	Start: Mar. 2025 Completion: Jun. 2026	India

Vaccine Candidate	Vaccine Type	Sponsor(s) and Major Partners	Status ^a	
Phase I NCT06438978	Safety, reactogenicity, and immunogenicity of MTBVAC (single arm)	30 IGRA- adults aged 18–65 years	Start: Jan. 2024 Completion: Jul. 2024	India
GamTBvac	Protein/adjuvant subunit vaccine	Gamaleya Federal Research Center for Epidemiology & Microbiology, Ministry of Health of the Russian Federation	Phase III	
Phase III NCT04975737	Efficacy, safety, and immunogenicity of GamTBvac vs. placebo POR, POD	9,500 adults aged ≥18 years Stage 1: 354 no history of TB disease and TST- Stage 2: 2,146 history of TB disease with cure Stage 3: 7,000 no history of TB disease and TST-	Start: Sep. 2022 Completion: Dec. 2026	Russia
VPM1002	Live rBCG	SII, Serum Life Science Europe, ICMR, EDCTP	Phase III	
Phase III NCT03152903	Efficacy, safety, immunogenicity of VPM1002 vs. placebo POR	2,000 adults treated for drug-sensitive TB aged 18–65 years	Start: Dec. 2017 Completion: Dec. 2023	Bangladesh, India
Phase III NCT04351685 PriMe	Efficacy, safety, immunogenicity of VPM1002 vs. BCG POI	6,950 HIV-exposed and unexposed infants aged 0–14 days	Start: Nov. 2020 Terminated: Oct. 2024 Results: Lancet Infect Dis	Gabon, Kenya, South Africa, Tanzania, Uganda
Phase III CTRI/2019/01/017026 PreVenTB	Efficacy, safety, immunogenicity of VPM1002 and MIP (Immuvac) vs. placebo POD	12,722 household contacts TST+/- aged >6 years	Start: Jul. 2019 Completion: Jul. 2024 Results: The BMJ	India
PreVenTB follow-up CTRI/2026/04/107798	Long-term follow-up for effectiveness of VPM1002 vs. placebo POD	8,478 household contacts aged >6 years from VPM1002 and placebo arms of PreVenTB trial followed 5–6 years post-vaccination	Start: Apr. 2026	India
ID93/GLA-SE (QTP101)	Protein/adjuvant subunit vaccine	Quratis, AAHI, U. Oxford, U.S. NIH, Afrigen, TBVI	Phase IIb/III	
Studies of ID93/GLA-SE sponsored by Quratis				
Phase IIb/III PHRR241120-007782	Efficacy, safety, and immunogenicity of ID93/GLA-SE vs. placebo POD	Phase IIb: 288 IGRA+/- adolescents and adults aged 14–55 years Phase III: 8,778 IGRA-positive adolescents and adults aged 14–55 years	Start: TBD Completion: TBD	Philippines, South Korea
Phase I NCT06714513	Safety and immunogenicity of ID93/GLA-SE vs. placebo	144 IGRA+/- adults aged 55–74 years	Start: May 2025 Completion: Dec. 2026	South Korea

Vaccine Candidate	Vaccine Type	Sponsor(s) and Major Partners	Status ^a	
Other studies of ID93/GLA-SE				
Phase IIb/III NCT06205589 A5397/HVTN 603 	Therapeutic efficacy, safety, and immunogenicity of ID93/GLA-SE vs. placebo when given during TB treatment RX VAX	1500 HIV+/- adults being treated for DS-TB aged 18–65 years	Start: Jan. 2027 Completion: Oct. 2029	HVTN/ACTG sites, including South Africa
Phase Ib NCT06670755	Safety and immunogenicity of ID93/GLA-SE given with BCG aerosol challenge	48 IGRA- adults aged 18–55 years	Start: Dec. 2024 Completion: Jul. 2027	United Kingdom
RUTI	Fragmented MTB	Archivel Farma	Phase IIb	
Phase IIb NCT04919239	Safety and efficacy (sputum culture) RX VAX	140 adults aged ≥18 years receiving treatment for DS-TB or MDR-TB	Start: Sep. 2021 Completion: Jun. 2025	India
Phase II NCT05455112	Safety and efficacy (early bactericidal activity) RX VAX	41 adults aged ≥18 years receiving treatment for DS-TB	Start: Oct. 2022 Completion: Oct. 2024	Argentina
a. Status indicates the most advanced phase of either ongoing or recently completed trials. b. Completion = study completion date on ClinicalTrials.gov, or date of “last participant, last visit.” Trial includes PLHIV  BCG = Bacille Calmette-Guérin vaccine DS-TB = drug-sensitive TB EDCTP = European and Developing Countries Clinical Trials Partnership FAP = Fundação Ataulpho de Paiva Gates MRI = Gates Medical Research Institute ICMR = Indian Council of Medical Research IGRA = interferon-gamma release assay MDR-TB = multidrug-resistant TB POD = prevention of disease POI = prevention of infection POR = prevention of recurrence RX VAX = therapeutic vaccination SII = Serum Institute of India TBVI = TuBerculosis Vaccine Initiative TPT = TB preventive treatment Sources: Information compiled from ClinicalTrials.gov and other clinical trial registries as of 2026 October 1. Information checked against pipeline published by the Stop TB Partnership Working Group on New TB Vaccines and supplemented with information provided to TAG by sponsors.				

VPM1002: Writing Its Final Chapter?

Two of three VPM1002 phase III trials published results in 2026. The first was an ICMR-funded POD study that opened in 2019 known as PreVenTB. The second was an infant POI trial called PriMe that evaluated VPM1002 as an alternative to BCG with funding from the EDCTP, European Investment Bank, and German Aerospace Center (DLR).

VPM1002 PreVenTB Results

The PreVenTB trial targeted a high-risk population that is typically excluded from TB vaccine research: household contacts of people with TB disease. The trial enrolled 12,722 HIV-negative household contacts aged six years and older across six Indian states. This was a three-arm study: participants were randomized to receive either VPM1002, a second experimental vaccine called **MIP (Immuvac)**, or placebo. The primary outcome was prevention of microbiologically confirmed TB disease over 38 months of follow-up; notably, the primary endpoint included both pulmonary and extrapulmonary TB. Secondary objectives assessed safety, immunogenicity, prevention of MTB infection (among a subset of participants who received a **TST** at baseline), and efficacy in predefined age groups.³⁸ There is a lot to unpack from the trial; the discussion here focuses on findings related to the primary endpoint that have generated significant discussion.

Neither VPM1002 nor MIP met the primary endpoint. The BMJ paper presented results from both the per-protocol and **mITT** analyses; the following discussion focuses on the mITT population (12,635 participants), which the **trial protocol** defined as the primary analysis. In the mITT analysis, 73 participants in the VPM1002 arm, 99 in the MIP arm, and 88 in the placebo arm developed TB.³⁹ Table A summarizes the mITT primary efficacy analysis.

MIP (Immuvac) is constructed from heat-killed, whole-cell *Mycobacterium indicus pranii* (MIP), an organism closely related to MTB.

TST = tuberculin skin test, a type of test for MTB infection.

mITT = modified intention to treat, an analysis that excludes some participants, often those who do not start the intervention after being enrolled.

According to the PreVenTB **trial protocol**: “The primary analysis, that is, mITT will include all randomised participants who have received at least one dose of vaccine/placebo excluding coprevalent cases.”

Table A: PreVenTB mITT Primary Efficacy Results

mITT analysis	No. participants who developed TB (%)		Vaccine efficacy (95% CI)
	VPM1002 N=4,207	Placebo N=4,223	
All TB	73 (1.74%)	88 (2.08%)	16.9 (-13.3 to 39.1)
Pulmonary TB	63 (1.5%)	73 (1.173%)	13.6 (-21.1 to 38.3)
Extrapulmonary TB	15 (0.36%)	26 (0.62%)	42.3 (-9.1 to 69.4)
	Immuvac N=4,205	Placebo N=4,223	
All TB	91 (2.16%)	88 (2.08%)	-4 (-39.4 to 22.5)
Pulmonary TB	80 (1.9%)	73 (1.173%)	-10.2 (-51.3 to 19.8)
Extrapulmonary TB	16 (0.38%)	26 (0.62%)	38.1 (-15.4 to 66.8)

Investigators acknowledged that “neither vaccine provided protection against TB in general,” but highlighted the higher vaccine efficacy against extrapulmonary TB and concluded that “protection was provided against extrapulmonary TB by both vaccines.” The authors cited the per-protocol analysis, where the efficacy of VPM1002 against extrapulmonary TB was 50.4% (95% CI 0.8% to 75.2%). They interpreted this as VPM1002 reducing extrapulmonary TB incidence “by more than 50%” and called on “policy makers [to] consider . . . the potential economic benefits of this reduction.”⁴⁰

This conclusion should be read with several qualifiers in mind. The efficacy signal against extrapulmonary TB arises from the per-protocol analysis but weakens in the mITT analysis (where VPM1002 efficacy against extrapulmonary TB was 42.3% [95% CI -9.1 to 69.4]).⁴¹ And although efficacy is higher against extrapulmonary TB than all-TB or pulmonary TB, it is modest (below 50% for both vaccines in the mITT population and just over 50% in the per-protocol analysis for VPM1002). The wide confidence intervals reflect substantial uncertainty and the relatively small number of events (57 people developed extrapulmonary TB: 15 in the VPM1002 group, 16 in the Immuvac group, and 26 who received placebo). In the mITT analysis, the confidence intervals cross zero (indicating statistical nonsignificance) and just barely avoid zero in the per-protocol analysis.

Investigators pointed to a glimmer of efficacy in a post-hoc analysis by age in which VPM1002 appeared to reduce TB incidence among participants 6–14 years old. This was reported as VPM1002 showing 64.6% efficacy (95% CI 16.3 to 85.1) against all-TB and 73.2% efficacy (95% CI 25.3 to 92.2) against extrapulmonary TB in children aged 6–14 among the per-protocol population.⁴² The paper presented this as a post hoc analysis, meaning it was performed after data were seen, and the subgroup of participants analyzed here did not match the age bands in the pre-specified analysis by age (where the age groups were 6–18, 19–35, 36–60, >60). In the prespecified age analysis, VPM1002 efficacy was not observed except against extrapulmonary TB in one age group (36–60) and only after a statistical correction was applied. In the post hoc analysis, the efficacy against extrapulmonary TB among 6- to 14-year-olds was only significant after applying the same statistical technique, called “Haldane’s modification,” which is used when a small number of people experience an outcome.⁴³

The PreVenTB trial results have a lot to teach the field, and the summary here only skims the surface. Perhaps the best word to describe these findings is “equivocal,” in the sense of inspiring multiple interpretations. Referring to the efficacy against extrapulmonary TB, the Stop TB Partnership posted an emphatic endorsement to LinkedIn: “Lets go for this – policy makers and regulators must act now! [sic]”⁴⁴

So far, the policy makers and regulators who have weighed in have had different ideas.

In a letter to *The BMJ*, the WHO Technical Advisory Group on TB vaccines shared its position: “We believe that interpretation of results warrants careful appraisal.” The group cautioned “against over-interpretation of secondary

exploratory endpoints to avoid misinforming policy makers, funders, and affected communities.”⁴⁵ Before publication of the *BMJ* paper, SII had applied with India’s Central Drugs Standard Control Organization (CDSCO) to obtain marketing authorization for VPM1002. Minutes from an October 15, 2025, CDSCO Special Expert Committee meeting recommended against approval, describing the efficacy observed in the post hoc analyses as inconclusive:

“[T]he committee deliberated the proposal extensively and recommended that the study data with post hoc analysis was not adequate and conclusive to take considered decision for the new drug application.”⁴⁶

The committee did, however, point to a potential path forward: “The firm should plan [an] adequately powered study based on the outcome of secondary endpoint of ICMR study for conclusive decision.”

In a letter responding to the WHO Technical Advisory Group, two former ICMR directors — Balram Bhargava and Soumya Swaminathan — defended the attention paid to the “two high-efficacy signals” against extrapulmonary TB, saying: “In TB, where trials are slow, secondary or post hoc signals should not be overlooked when biologically grounded.”⁴⁷ The slowness of TB trials should not dilute the rigor with which results are judged, but the point hits on a certain truth: efficacy signals seen in secondary analyses can become magnets for hope in a field with limited resources and relatively few major trials. A recent example is the phase II trial of BCG revaccination in South African adolescents, which failed to reproduce a signal observed on a secondary endpoint in a smaller study (read last year’s *Pipeline Report* for a discussion of those results).^{48,49}

Bhargava and Swaminathan did not make the case for immediate policy change based on the PreVenTB trial but did call for further evaluation of VPM1002 efficacy against extrapulmonary TB, in general, and against pulmonary and extrapulmonary TB in young children “through implementation or phase IV studies.”⁵⁰ PreVenTB principal investigator Manjula Singh made a similar point in a viewpoint piece accompanying the *BMJ* paper, calling out the mismatch between the substantial public health burden of extrapulmonary TB and the dearth of trials seeking better ways to prevent it:

“We need to change the way we design tuberculosis vaccine trials to show the full preventive potential of vaccines, to help inform policy makers around the world when considering the adoption of vaccines depending on need.”⁵¹

Will VPM1002 enter future trials testing its efficacy against (extra)pulmonary TB? Serum Life Science Europe told TAG that additional studies of VPM1002 are being explored but did not indicate what options are on the table.⁵² SII gave TAG some additional detail: “ICMR is planning a large phase III study in pediatric population 6-to-14 years of age for prevention of TB disease. There are plans for implementation studies in a few countries, but these are at [a] very nascent

stage.”⁵³ Meanwhile, ICMR is continuing **long-term follow-up** of participants in the VPM1002 and placebo arms of the PreVenTB trial to assess the effectiveness of the vaccine out to five-to-six years post-vaccination.

PreVenTB **long-term follow-up** study
CTRI/2026/04/107798.

VPM1002 PriMe Results

The **PriMe** trial enrolled 6,950 infants aged 0–14 days in five African countries: Gabon, Kenya, South Africa, Tanzania, and Uganda. Randomization was stratified by maternal HIV status, and the trial enrolled 720 infants born to mothers living with HIV.

Phase III VPM1002 infant trial (**PriMe**) NCT04351685.

Infant vaccines have taken a backseat in global TB R&D efforts over the last decade in favor of vaccines that can prevent TB disease in adolescents and adults, which the WHO has described as “the priority strategic target in TB vaccine development.”⁵⁴ Although a secondary goal, developing new infant vaccines that improve on BCG remains an important public health objective. Infants may not drive TB transmission, and therefore new vaccines for this age group would have a less immediate effect on reducing TB incidence than adolescent and adult vaccines, but young children are highly vulnerable to TB and deserve safe, effective prevention options. The WHO has laid out preferred product characteristics for infant vaccines, saying that, among other qualities, they should offer superior efficacy and better safety than BCG.⁵⁵

Judged against these criteria, several elements of the PriMe trial are surprising. First, the trial’s primary outcome was prevention of infection — not prevention of disease. The primary efficacy analysis compared VPM1002 with BCG in terms of occurrence of IGRA conversion (using the QuantiFERON-TB Gold Plus test, hereafter QFT), with a positive test indicating MTB infection.⁵⁶ (Secondary endpoints evaluated efficacy against TB disease and sustained infection.) Second, the study was designed as a noninferiority — not a superiority — trial. In general terms, noninferiority trials ask whether an intervention is “no worse than” an established standard of care within a prespecified allowance (called a noninferiority margin). Superiority trials, on the other hand, test whether an intervention is better than the comparator. Here, the noninferiority margin corresponded with VPM1002 retaining at least 75% of BCG’s protection. Noninferiority would be achieved if the upper bound of the 95% confidence interval for the hazard ratio was less than 1.25.⁵⁷

Even if the trial had proceeded smoothly, the MTB infection endpoint and the noninferiority design set up PriMe for a rough road toward changing global BCG vaccination policy. But things did not go smoothly. Like most TB vaccine efficacy trials, this one was event driven, meaning the primary analysis would be triggered by observing a certain number of endpoints; in this case, 632 QFT conversions. When designing the trial, investigators had assumed an annual IGRA conversion rate of 5.5%. The main source of trouble was a much lower rate of 2.6–2.7%. This prompted investigators to extend follow-up from 36 to 48 months, but time

was not on their side: as children age, vulnerability to TB decreases and rates of MTB infection drop off. By August 2024, nearly four years after opening, the trial had accrued just over half of the required events (334 of 632), and the sponsors decided to stop the study early: “The trial was terminated in October 2024, following review by the data safety monitoring board and sponsor decision. No prespecified futility boundary was crossed; the decision reflected the practical judgment that further follow-up would not yield sufficient additional events.”⁵⁸

In the end, VPM1002 was not noninferior to BCG. There were 184 QFT conversions among 3,471 participants in the VPM1002 group and 150 among 3,469 in the BCG group.⁵⁹ This yielded a hazard ratio of 1.23 (95% CI 0.99 to 1.53) with the upper bound of the confidence interval exceeding the threshold of 1.25 and thus not achieving noninferiority. Secondary efficacy endpoints also favored BCG. There were 44 sustained QFT conversions in the VPM1002 group and 18 in the BCG group. Eighteen participants who received VPM1002 developed microbiologically confirmed TB disease versus six participants who received BCG. Unconfirmed tuberculosis occurred in 92 participants in the VPM1002 group compared with 53 in the BCG group.⁶⁰

Was VPM1002 actually worse than BCG? Strictly speaking, it’s difficult to say: early termination left the trial underpowered, with half as many endpoints as planned. Differential TB exposure between the two arms further complicates interpretation. Infants in the VPM1002 group had more TB exposure than those vaccinated with BCG. This violated “a fundamental assumption of any infection-based endpoint that pathogen exposure is balanced between groups.”⁶¹ When higher TB exposure was accounted for in a post hoc analysis, the two groups had similar QFT conversion rates. The study team concluded that “the trial therefore does not support a definitive conclusion of VPM1002 inferiority.”⁶²

One thing is clear: POI efficacy trials that use IGRAs to define primary endpoints are laden with risk. In an editorial accompanying the results in *Lancet Infectious Diseases*, TB vaccinologist Helen McShane summarized the myriad problems IGRAs pose to the clinical trialist: “Reversions from positive to negative, indeterminate results, and false positives are all common, reducing predictive value.”⁶³ The PriMe investigators framed the IGRA-based primary endpoint as a “pragmatic calculation,” saying: “infection events occur more frequently than disease events, permitting a smaller sample size and shorter follow-up than would be required for a disease powered trial.”⁶⁴

That pragmatic calculation turned out to be a costly bargain. PriMe is the field’s **third POI trial** to disappoint. In TAG’s view, until it is possible to ascertain MTB infection with more precise tools than IGRAs, developers should design efficacy trials around prevention-of-disease endpoints.

Three POI trials have returned negative results:

- 2020: DAR-901
[NCT02712424](#)
- 2024: BCG
revaccination
[NCT04152161](#)
- 2026: VPM1002
[NCT04351685](#)

MTBVAC: Charting a “Little Universe” of Activity

The conclusion of the PriMe trial leaves the field with a single study in infants: a **phase III trial of MTBVAC**. Compared with VPM1002, the MTBVAC infant study more closely reflects the WHO *Preferred Product Characteristics*; it is designed to show superior protection of MTBVAC over BCG with a POD primary endpoint. The trial reached full enrollment in August 2026.⁶⁵ Most of the 7,120 enrolled infants are from South Africa, with smaller cohorts contributed by sites in Madagascar and Senegal.

Phase III trial of MTBVAC
in infants [NCT04975178](#).

The phase III infant trial is just one star in what Rolando Pajón, chief medical and scientific officer at Biofabri, has described as the “little universe” of the MTBVAC development program.⁶⁶ At the center of that universe is Biofabri, a Spanish biotech company serving as the lead sponsor of MTBVAC, which was developed at the University of Zaragoza. MTBVAC is a mycobacterial vaccine constructed from a clinical isolate of MTB attenuated through the deletion of two genes encoding major virulence factors: *phoP* and *fadD26*. The identification of *phoP* as an important target for attenuation was made by studying an unusual strain of drug-resistant *Mycobacterium bovis* that caused a TB outbreak in Spain in the early 1990s, killing 100 people living with HIV.⁶⁷

The “distinctly Spanish pedigree”⁶⁸ of MTBVAC has taken on an international flavor with manufacturing partners in India (Bharat Biotech) and Brazil (**FAP**) and clinical, regulatory, and policy support from IAVI. The universal nature of the program is integral to Biofabri’s goal of positioning MTBVAC as a global health vaccine backed by an ambitious access strategy. The licenses between Biofabri and Bharat Biotech and FAP have given each the rights to supply MTBVAC to specific geographies, with Bharat Biotech covering Africa and most of Asia (81 countries), FAP responsible for the Americas (34 countries), and Biofabri serving 85 high-income markets in North America, Europe, and other countries. Technology transfer from Biofabri to Bharat Biotech began in 2026 and is expected to begin soon at FAP.⁶⁹

FAP = Fundação
Ataulpho de Paiva.

MTBVAC’s access-forward orientation is becoming almost a brand identity. At the International AIDS Conference in Rio de Janeiro, the Spanish Ministry of Health convened a high-level meeting to discuss MTBVAC as a case study in “access-first innovation.”⁷⁰ Implicit in this framing is an unspoken contrast between MTBVAC and the other pipeline frontrunner: M72/AS01E. While M72/AS01E was first to phase III, it took longer than MTBVAC to identify commercial partners. Where M72/AS01E requires two doses, MTBVAC is single dose. Where M72/AS01E is a subunit vaccine that combines protein and adjuvant components — one of which, the GSK-controlled AS01E adjuvant, contains key ingredients reliant on natural sourcing⁷¹ — MTBVAC touts its streamlined manufacturing requirements and low cost of goods. Taken individually, these are just points of difference. What draws a discernible contrast between MTBVAC and M72/AS01E is something both vaccines share: the timing of efficacy results.

The M72 Partners have consistently flagged 2028 as the year by which phase III trial results will be available, with regulatory policy submissions following in 2029. The assumption was that MTBVAC efficacy data would follow a year or two behind M72/AS01E. Recently, Biofabri has begun touting 2028 as “the year of efficacy,”⁷² bringing MTBVAC into more direct comparison with M72/AS01E. This rests on having interim results from two ongoing trials: the infant phase III trial mentioned above and a phase IIb study among 5,500 adolescents and adults (14–45 years) in Kenya, South Africa, and Tanzania.

Sponsored by IAVI and known as **IMAGINE**, the phase IIb trial reached full enrollment on July 16, 2026.⁷³ The primary endpoint is prevention of bacteriologically confirmed pulmonary TB disease (with a similar case definition as the M72/AS01E phase III trial). When it first opened, in February 2025, the trial aimed for a total enrollment of 4,300 IGRA-positive participants. With funding from Coefficient Giving, the trial added a cohort of 1,200 IGRA-negative participants to generate safety and immunogenicity data in people without MTB infection.⁷⁴ The primary analysis remains powered on the IGRA-positive cohort and will occur when investigators observe 35 cases of TB.

Phase IIb **IMAGINE** trial of MTBVAC NCT06272812.

Funding for IMAGINE comes from the Gates Foundation, Coefficient Giving, and EDCTP.

Biofabri shared with TAG that both the infant trial and IMAGINE have interim analyses set to occur in early 2028. If a positive efficacy signal is observed here, Biofabri plans to approach the European Medicines Agency for conditional marketing authorization.⁷⁵ What would essentially be an accelerated approval would rest on the strength of the efficacy signal, the demonstration of public health need, and the provision of additional confirmatory data. For infants, a conditional authorization could be converted to full approval if final results from the phase III trial (expected in 2029) confirm the interim signal. For adolescents and adults, however, full approval would likely require data from a larger study: a positive readout from a phase IIb study like IMAGINE would ordinarily be taken as “proof of concept” setting up a confirmatory phase III trial aimed at licensure.⁷⁶

Bharat Biotech has announced plans to launch a phase III trial of MTBVAC at sites across India in late 2026. The study did not have a clinical trials registry number at the time of publication, but a few details were shared with TAG. The trial will run from 2026 to 2031 and, with over 25,000 participants, will be the largest TB vaccine efficacy trial of the twenty-first century. The primary endpoint is prevention of microbiologically confirmed pulmonary TB disease (with similar case definitions used in IMAGINE and the M72/AS01E phase III trial) in IGRA-positive individuals, who will comprise most participants. A smaller cohort of IGRA-negative people will also be enrolled.⁷⁷

MTBVAC in PLHIV

A major unanswered question for MTBVAC is whether the vaccine is safe to use in PLHIV. As a live attenuated vaccine, one constructed from the target pathogen itself, MTBVAC poses safety concerns in PLHIV and other immunocompromised

people that require careful interrogation. Pajón has said Biofabri is “being very cautious in how we approach it.”⁷⁸ Two studies — one ongoing, one planned — will address this question.

The ongoing study is a **phase II trial** evaluating the safety and immunogenicity of MTBVAC in 279 adolescents and adults living with HIV in South Africa. Originally funded by the U.S. NIH and conducted by the HVTN and **ACTG**, this trial had to be rescued from the fallout of a White House executive order banning U.S. foreign aid or assistance to South Africa. The NIH lifted the prohibition on funding for South Africa in August 2026 — rightly concluding that its grantmaking is distinct from foreign assistance and therefore not subject to the executive order⁷⁹ — but by then the trial had secured **outside funding** and switched its sponsorship to the Fred Hutch. The study reopened enrollment in June 2026 and expects to reach last participant, last visit around December 2027.⁸⁰

The study includes three cohorts enrolled in two distinct stages. The first stage includes 84 HIV-negative individuals (cohort 1) and 108 people with well-controlled HIV (cohort 2), defined as being on ART, virally suppressed, and with a CD4 T-cell count ≥ 200 cells/mm³. Results from these two cohorts were presented at the June CTVD meeting in Nairobi, Kenya. The emerging data paint a picture of a candidate that is safe and immunogenic in these cohorts and supported proceeding to the second stage of the study and cohort 3.⁸¹ This third cohort focuses on a more vulnerable population: people with signs/symptoms of HIV immunosuppression. Cohort 3 participants must be on ART, virally suppressed, and with CD4 ≥ 100 cells/mm³ at time of enrollment.

The safety and immunogenicity data from the Fred Hutch–sponsored study will be important but not sufficient in determining the safety of MTBVAC in PLHIV. The study is relatively small: of 279 total participants, only 136 PLHIV will be randomized to receive MTBVAC. To generate additional safety data in PLHIV, Biofabri is working with IAVI and the HVTN to design a larger HIV-focused study that will run parallel to IMAGINE and Bharat Biotech’s phase III trial.⁸² The three partners are consulting with funders, regulators, HIV experts, and community representatives on the study’s design.

Together, these two trials are proceeding in line with standards set by an international consensus statement on studying TB vaccines in PLHIV. That document essentially said PLHIV can be included in phase II and III trials of live attenuated vaccines like MTBVAC if they have CD4+ T-cell counts ≥ 100 cells/mm³ or HIV RNA < 200 copies/mL.⁸³ But this raises an important question: what about people with HIV who are undiagnosed, unaware of their status, and/or living with **advanced HIV disease**? This last group is most at risk of receiving a live mycobacterial vaccine but also the most difficult to study. Once someone is diagnosed with HIV, they are eligible to begin ART. It would be unethical to enroll people of unknown HIV status, or to delay ART initiation among those newly diagnosed in the trial, making it nearly impossible to generate robust safety data

Phase II trial of MTBVAC in PLHIV [NCT05947890](#).

ACTG = Advancing Clinical Therapeutics Globally.

The MTBVAC phase II trial in PLHIV in South Africa secured **outside funding** from Coefficient Giving.

WHO defines **advanced HIV disease** (AIDS) as CD4 < 200 cells/mm³ or a clinical stage 3 or 4 AIDS-defining illness/event.

on MTBVAC in this population in the clinical research setting. An absence of safety data, however, would leave risks undefined in practice — for example, in the context of a general vaccination campaign. There are consequences at both the individual and societal levels: a major safety event in someone with undiagnosed HIV would not only harm that individual but would also jeopardize the larger vaccine drive and undermine trust in vaccines. Countries with high HIV prevalence may therefore elect to require HIV testing before vaccination with MTBVAC, a condition that would add cost and complexity.

QTP101 (ID93/GLA-SE): Pursuing Multiple Paths through Middle Development

The vaccine candidate known by two names — QTP101 (née ID93/GLA-SE) — is pursuing multiple paths through middle development with a raft of planned phase II studies. A protein/adjuvant vaccine, ID93/GLA-SE combines four MTB antigens (Rv3619, Rv1813, Rv3620, and Rv2608) with the **GLA-SE** adjuvant.

The phase II journey for ID93/GLA-SE can be viewed several ways. One can sort clinical trials into those sponsored by South Korean biotech Quratis, or those led by outside partners. One can look to indication, distinguishing studies evaluating ID93/GLA-SE against prevention of disease versus other endpoints. Or one can separate studies using the original two-vial presentation of the vaccine (separate vials for the ID93 antigen and GLA-SE adjuvant) from those that will use a single-vial, **lyophilized** formulation under development.

Let's take it by sponsor.

Quratis, which refers to ID93/GLA-SE as QTP101, obtained the vaccine through a technology transfer agreement with the Seattle-based Infectious Diseases Research Institute (which emerged from bankruptcy several years ago as **AAHI**). Since licensing QTP101, Quratis has completed two phase I/II studies of the vaccine in IGRA-negative **Korean adolescents** and **health care workers**. An ongoing phase I study is assessing ID93/GLA-SE safety and immunogenicity among 144 IGRA-positive and IGRA-negative **older adults** (55–74 years) in South Korea. These studies are prelude to a larger phase IIb/III efficacy trial that Quratis has been building toward for several years. Plans for that trial have shifted over the years but are starting to come into firmer focus.

Quratis confirmed that it is preparing to open a **phase IIb/III POD trial** in South Korea and the Philippines that will enroll over 9,000 adolescents and adults aged 14–55 years. A description of the trial is now available on the website of the **Philippines clinical trials registry**. The study will occur in two stages. Stage 1 will enroll 288 IGRA-positive and IGRA-negative participants to receive either ID93/GLA-SE at a single dose level (10 mg ID93 plus 5 mg GLA-SE) or placebo. Because this dose has not previously been evaluated in IGRA-positive participants in Quratis-sponsored studies, stage 1 will assess its safety and immunogenicity in this population before proceeding to the second trial stage.⁸⁴ Stage 2 will enroll

GLA-SE combines glucopyranosyl lipid A (GLA) with an oil-in-water emulsion using squalene (SE). It acts as a TLR4 agonist.

Lyophilization is essentially freeze-drying and improves the thermostability of vaccines, making them more suitable for real-world conditions.

AAHI = Access to Advanced Health Institute.

QTP101 phase I study in **Korean adolescents** (NCT03806699), phase IIa study in **health care workers** (NCT03806686), and phase I study in **older adults** (NCT06714513).

Phase IIb/III POD trial of ID93/GLA-SE sponsored by Quratis has been posted on the **Philippines clinical trials registry** [PHRR241120-007782](https://www.philippineclinicaltrialsregistry.com/PHRR241120-007782).

8,778 IGRA-positive adolescents and adults to receive the same dose of ID93/GLA-SE or placebo. The trial will make use of the existing two-vial presentation of ID93/GLA-SE and administer the vaccine as three intramuscular injections spaced 28 days apart.

In addition to Quratis-sponsored trials, ID93/GLA-SE is advancing through several other partnerships:

- Oxford University is conducting a **phase Ib trial** generating safety and immunogenicity data on ID93/GLA-SE when given in an aerosol BCG challenge model among 48 BCG-vaccinated and BCG-naïve adult volunteers.
- The ACTTIVAC partnership, led by the TuBerculosis Vaccine Initiative (TBVI) with EDCTP funding, is advancing the lyophilized, single-vial formulation of ID93/GLA-SE mentioned above.⁸⁵ The project includes funding for a phase IIa trial that will test this new formulation at four different dose levels to select a dose and regimen for future phase IIb work. ACTTIVAC will also support work between AAHI and **Afrigen Biologics** to establish readiness to produce GMP grade GLA-SE, including a novel version of the adjuvant using a plant-based alternative to squalene, which is traditionally sourced from shark liver oil. The project revives the promise of an earlier collaboration: before it became AAHI, IDRI licensed ID93/GLA-SE to both Quratis and Afrigen. Afrigen completed technology transfer for lab-scale GLA-SE in 2016 but has not pursued much activity on the product until now.⁸⁶
- The fate of an ACTG and HVTN **phase II/III trial** of ID93/GLA-SE given as a therapeutic vaccine was thrown into doubt by Trump Administration attacks against the NIH (the original plan was to conduct the study in South Africa). Investigators are recoalescing and hope to open the study in early 2027 with several changes: sponsorship has shifted from the ACTG to the HVTN, the trial will use vaccine manufactured by Quratis (not **AAHI**), and the trial will now include sites outside of South Africa (though South African sites are likely to rejoin).⁸⁷ Owing to the vicissitudes of NIH funding precarity, the study may open a smaller phase IIa stage before securing support for the phase IIb component (up to 1500 total participants).⁸⁸ The idea behind the study is to see if giving ID93/GLA-SE at different time points in TB treatment reduces TB-related unfavorable outcomes (treatment failure, TB recurrence, or death due to TB). The trial will be the first to test ID93/GLA-SE in PLHIV.

Phase Ib trial of ID93/GLA-SE given in BCG challenge model [NCT06670755](#).

Based in Cape Town and home to the mRNA Technology Transfer Hub, **Afrigen Biologics** is a nonprofit vaccine innovator and manufacturer.

Phase II/III trial of ID93/GLA-SE as a therapeutic vaccine [NCT06205589](#)

In 2025, **AAHI** selected Quratis as its “preferred manufacturer,” touting Quratis’s GMP-certified plant in Osong, South Korea.

GamTBvac **phase III trial** [NCT04975737](#).

CpG ODN = cytosine-phosphodiester-guanine (CpG) oligonucleotide (ODN). CpG ODNs adjuvants act as TLR9 agonists.

GamTBvac: Making a Surprising Turn

The protein/adjuvant vaccine GamTBvac, developed by Russia’s Gamaleya Federal Research Center for Epidemiology & Microbiology, began a **phase III trial** in 2021. GamTBvac combines three MTB antigens (ESAT-6, CFP10, and Ag85A), joined by dextran-binding domain from *Leuconostoc mesenteroides*, with a **CpG ODN** adjuvant.⁸⁹

TAG has not reported extensively on the GamTBvac phase III study since it was first registered on ClinicalTrials.gov as a POD trial among 7,180 **TST**-negative adults. That last detail always stood out; most POD trials target enrollment toward people with MTB infection (usually marked by positive IGRAs), since they are more likely than uninfected individuals to develop disease within the timespan of clinical trials. At the time, Gamelaya's Maria Semashko told TAG that the focus on individuals without MTB infection satisfied a request by Russian health authorities to conduct the phase III trial among the same population in which safety was demonstrated in prior phase I/II trials.⁹⁰

The use of **TST** — here Diaskintest or Mantoux — is notable as most trials use IGRAs to define MTB infection.

In July 2026, the trial's ClinicalTrials.gov page recorded its first change since 2022. The updated entry represents a major overhaul of the study design. The trial now has three stages and a total sample size of 9,500. Essentially, the trial sandwiches a POR study (Stage 2) within a larger POD trial (Stages 1 and 3).⁹¹

In Stage 1, 354 participants will receive either two doses of GamTBvac or placebo. The primary endpoint is “incidence rate of respiratory tuberculosis.”

Stage 2 will enroll 2,146 people previously treated for pulmonary TB and evaluate whether GamTBvac prevents recurrent disease. Participants in this stage are described as people cured of active pulmonary TB without major “residual changes” (i.e., lung pathology) and judged to be at low risk of relapse. The primary endpoint will compare incidence of active pulmonary TB disease between the GamTBvac and placebo groups 24 months post-vaccination. Interestingly, the study record indicates that if efficacy is shown in Stage 2, the study will stop here without opening Stage 3:

“In the absence of statistically significant data on vaccine efficacy by Visit 6 (24 months ± 30 days), the study will proceed to Stage 3. In the event that statistically significant data on the prophylactic efficacy of GamTBvac are obtained by Visit 6 (24 months ± 30 days), the study will be terminated.”⁹²

TAG has learned that Stage 3 of the study opened for enrollment; a March 2025 report in **Pharmvestnik** confirms this, saying that Stage 2 finished without any major safety events and that Stage 3 is expected to finish around December 2026. Stage 3 is enrolling 7,000 participants without a history of active TB disease. Participants must have a negative skin test, indicating absence of MTB infection, to be eligible. Previously, enrollment was restricted to adults aged 18–45 years; the upper limit has now been removed. The primary endpoint for Stage 3 is prevention of disease.⁹³ TAG's source said that registration of GamTBvac in the Russian Federation is expected in 2027.

March 2025 **Pharmvestnik** report on the GamTBvac phase III trial.

Treatment Action Group thanks the TB vaccine developers, sponsors, and funders who responded to requests for information, and Jennifer Woolley at the Working Group on New TB Vaccines and Nebiat Gebreselassie at the World Health Organization for coordination on outreach.

Table 2: TB Vaccine Candidates in Earlier Stages of Development

Vaccine Candidate	Vaccine Type	Sponsor(s) and Major Partners	Status ^a	
Trial phase Registry no.	Trial description and endpoints	Study population	Timeline	Countries
BNT164a1 BNT164b1	mRNA	BioNTech	Phase IIa	
Phase Ib/IIa NCT05547464	Phase Ib: safety, immunogenicity, and dose-finding study Phase IIa: safety expansion in HIV-negative participants at two dose levels	497 IGRA+/- adults - Phase Ib: 197 IGRA+/- adults aged 18–55 years - Phase IIa: ~300 IGRA+/- adults aged ≥18 years	Start: Jul. 2023 Completion: ^b Jan. 2027	Mozambique, South Africa
Phase 1 NCT05537038	Safety, immunogenicity, and dose-finding	120 IGRA-negative adults aged 18–55 years	Start: Apr. 2023 Completion: Dec. 2025	Germany
H107e/CAF10b	Protein/adjuvant subunit vaccine	Statens Serum Institut	Phase I	
Phase Ia/Ib NCT06050356	Phase Ia dose-finding Phase Ib safety and immunogenicity	Phase Ia: 40 IGRA- adults aged 18–45 years Phase Ib: 100 IGRA+/- adults aged 18–45 years	Start: Mar. 2024 Completion: Dec. 2026	South Africa
TB/FLU-05E	Viral vector	Smorodintsev Research Institute of Influenza, Ministry of Health of the Russian Federation	Phase II	
Phase II NCT06873282	Safety and immunogenicity Intranasal	160 IGRA- adults aged 18–50 years	Start: Dec. 2023 Completion: Apr. 2024	Russia
Ad5-105K	Viral vector	CanSino Biologics, PT Etana Biotechnologies Indonesia	Phase I	
Phase I NCT06732583	Safety, immunogenicity, dose-finding Nebulized inhalation	36 IGRA+ adults aged 18–49 years	Start: Nov. 2025 Completion: Aug. 2026	Indonesia
RH119	mRNA	Rhegen Bio (Shenzhen Ruiji Biotechnology)	Phase I	
Phase I ChiCTR2500109630	Safety, immunogenicity, dose-finding	36 IGRA+ adults aged 18–59 years	Start: Mar. 2025 Completion: Sep. 2026	China
Phase I ChiCTR2400094049	Safety, immunogenicity, dose-finding	56 IGRA- adults aged 18–59 years	Start: Dec. 2024 Completion: Jun. 2026	China

Vaccine Candidate	Vaccine Type	Sponsor(s) and Major Partners	Status ^a	
LipovaxinS4-EAH	Self-adjuvanting liposomal recombinant protein	PT Bio Farma, Lipotek, Indonesia Ministry of Health	Phase I	
Phase I <u>NCT07647107</u>	Safety, immunogenicity, dose-finding	60 IGRA- adults aged 18–40 years	Start: Aug. 2026 Completion: Aug. 2027	Indonesia
HCMV-TB (VIR-1778)	Viral vector (rCMV)	HVTN/NIAID	Phase I	
Phase I <u>NCT07818824</u>	Safety, immunogenicity, dose-finding	116 CMV+, IGRA- adults aged 18–55 years	Start: Nov. 2026 Completion: Jun. 2028	Peru

a. Status indicates the most advanced phase of either ongoing or recently completed trials.

b. Completion = study completion date on ClinicalTrials.gov, or date of “last participant, last visit.”

BCG = Bacille Calmette-Guérin vaccine | CMV= cytomegalovirus | HVTN = HIV Vaccine Trials Network | IGRA = interferon-gamma release assay | NIAID = National Institute of Allergy and Infectious Diseases

Sources: Information compiled from ClinicalTrials.gov and other clinical trial registries as of 2026 October 1. Information checked against pipeline published by the Working Group on New TB Vaccines and supplemented with information provided to TAG by sponsors.

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