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Gates Medical Research Institute & Serum Institute of India to manufacture new TB vaccine candidate

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Successful Phase 3 clinical trials outcome is pending



The Gates Medical Research Institute (Gates MRI) has reached a milestone agreement with the Serum Institute of India (SII) to manufacture M72/AS01E, a novel tuberculosis (TB) vaccine candidate.

Currently in a Phase 3 clinical trial, M72/AS01E has the potential to be the first new TB vaccine to be introduced in more than a century, a potential breakthrough against a disease that remains the world's leading infectious cause of death and disproportionately impacts low- and middle-income countries.

With this partnership, Gates MRI and SII will begin the process of transferring the technology and know-how required to manufacture the antigen and enable future large-scale production of M72/AS01E.

SII expects to invest more than $100 million of its own resources to strengthen manufacturing readiness and capacity building to support potential future supply.

GSK, the original developer of the vaccine, will supply the AS01E adjuvant. Initiating this work well ahead of Phase 3 trial results is a deliberate strategy to ensure readiness to produce and distribute the vaccine and begin meeting global demand as quickly as possible, should the trial be successful and regulatory approvals be granted.

Gates MRI is sponsoring the Phase 3 clinical trial of M72/AS01E, with funding from the Gates Foundation and Wellcome. The double-blind, randomised trial, which started in March 2024, reached full enrollment in April 2025, of 20,000 participants in South Africa, Kenya, Malawi, Zambia, and Indonesia across 54 sites.