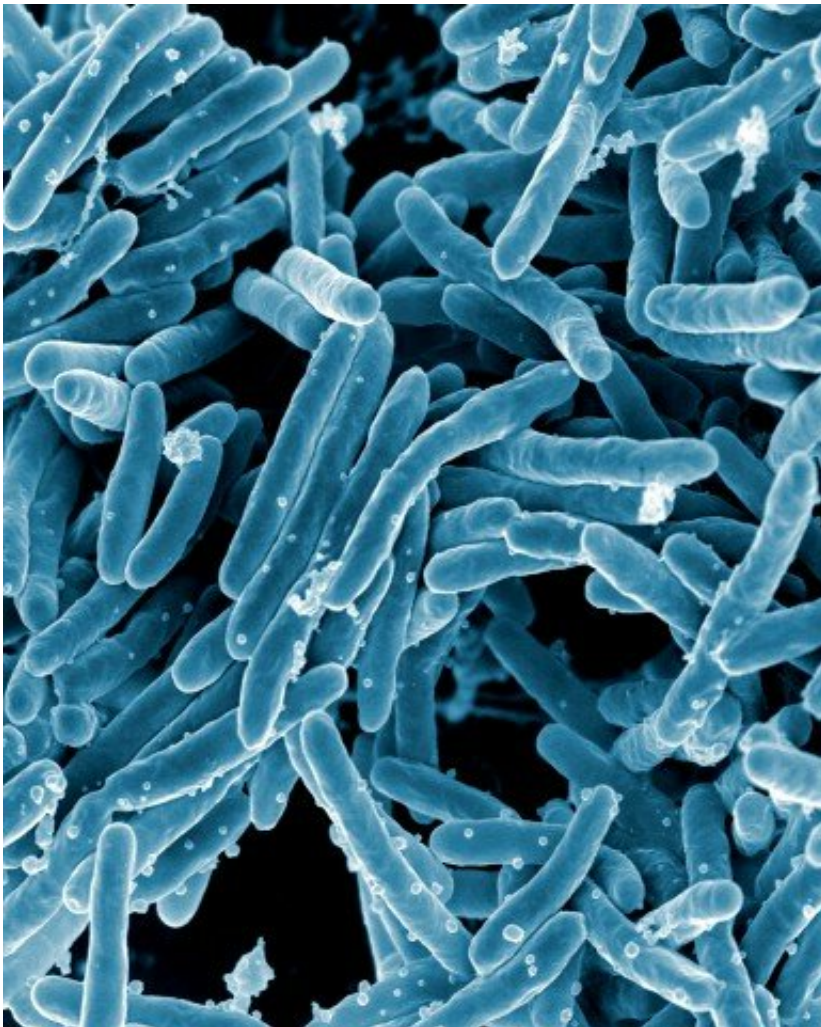


Temperature-stable experimental tuberculosis vaccine enters clinical testing

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Scanning electron micrograph of *Mycobacterium tuberculosis*. Credit: NIAID

Vaccinations have begun in a Phase 1 human clinical trial testing a freeze-dried, temperature-stable formulation of an experimental tuberculosis (TB) vaccine candidate. The trial is being conducted at the Saint Louis University School of Medicine Center for Vaccine Development and will enroll as many as 48 healthy adult volunteers aged 18 to 55 years. The experimental vaccine, called ID93, was developed by scientists at the Infectious Disease Research Institute (IDRI) in Seattle. The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, is supporting the trial through a contract to IDRI.

ID93 is a recombinant vaccine candidate made from four proteins of *Mycobacterium tuberculosis* (the bacterium that causes TB). Many vaccines require a temperature-controlled system during transport, which can be costly and logistically challenging. Freeze-dried powder vaccines can be distributed at a cheaper cost to remote, low-resource settings. The powder formulations are mixed with sterile water for administering with a needle and syringe. Investigators are examining if a powder formulation combining ID93 and the adjuvant GLA-SE (an [immune response](#)-stimulating protein) in a single vial, reconstituted with sterile water, is as effective at inducing an immune response in participants as the [previously tested](#) two-vial combination of powdered ID93 and liquid GLA-SE.

"Tuberculosis remains the leading infectious cause of death worldwide, and a highly effective vaccine would be a crucial tool in ending this pandemic," said NIAID Director Anthony S. Fauci, M.D. "A vaccine that did not require a cold chain could be much more easily distributed to communities in need."

Currently, Bacillus Calmette-Guérin (BCG) is the only Food and Drug Administration approved TB vaccine. It is commonly given to babies in TB-endemic regions to protect children against meningitis and

disseminated disease. However, the vaccine does not adequately prevent TB disease in adolescents and adults.

ID93 + GLA-SE is being developed as a vaccine candidate that could be administered to people who have already received the BCG vaccine or have already been exposed to TB, to prevent reactivation or reinfection. The vaccine was recently shown to be safe and immunogenic in a [Phase 2a clinical trial](#) that enrolled adults in South Africa who had recently been cured of TB with standard therapy. Other early-stage [clinical trials](#) showed ID93 + GLA-SE is safe and immunogenic in [healthy adults in the United States](#) and in [BCG-vaccinated adults in South Africa](#).

"To our knowledge, the freeze-dried formulation of ID93 + GLA-SE represents the first time a thermostable [vaccine candidate](#) containing a modern immune-boosting substance has reached clinical testing," said Christopher Fox, Ph.D., vice president of Formulations at IDRI and principal investigator of the NIAID contract. "Implementing technologies designed for low-resource settings early in product development could help accelerate vaccine rollout in hard-to-reach areas."

Daniel Hoft, M.D., Ph.D., director of the Division of Infectious Diseases, Allergy and Immunology at the Saint Louis University School of Medicine, is the principal investigator for the clinical trial. All participants will receive two vaccinations 56 days apart. Half of those enrolled (24 people) will receive the single-vial formulation of ID93 and GLA-SE, and the remaining participants will receive the previously tested two-vial presentation of powdered ID93 and liquid GLA-SE.

Participants will be monitored for any possible reactions to the [vaccine](#) and will be asked to provide blood samples at specified time points over approximately seven months. Investigators will examine the samples to determine if participants have generated an immune response. To ensure

the safety of participants, a safety monitoring committee composed of an independent group of experts will review safety data throughout the trial, which is expected to end in November 2020. For more information, visit [ClinicalTrials.gov](https://clinicaltrials.gov) and search identifier [NCT03722472](https://clinicaltrials.gov/ct2/show/study/NCT03722472)

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