

IAVI Announces First Vaccinations in a Phase I Trial of a Promising HIV Vaccine Approach

IAVI G004 study will examine safety and immune response to specialized immunogens that encourage production of broadly neutralizing antibodies.

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In 2024, 40.8 million people were living with HIV, and 1.3 million people newly acquired HIV.

The IAVI/Scripps Research HIV vaccine development strategy aims to coach the immune system to produce broadly neutralizing antibodies that could provide broad protection against HIV.

IAVI, a global nonprofit scientific research organization, announces that the first doses of experimental HIV vaccine antigens were administered on December 15, 2025, at the Perinatal HIV Research Unit in Soweto, South Africa, initiating the [IAVI G004 clinical trial](#).

IAVI G004 is designed to advance the IAVI/Scripps Research strategy for HIV vaccine development. The hypothesis being tested is that highly specialized vaccine immunogens, delivered in a specific sequence, can target certain B cells within the immune system and coach them toward the production of broadly neutralizing antibodies against HIV.

Scientists widely believe that a vaccine inducing broadly neutralizing antibodies (bnAbs) could provide broad protection against many strains of HIV. Using three immunogens developed by IAVI/Scripps Research delivered on Moderna's mRNA platform, this study will examine safety, immune responses, and dose levels.

[Editor's note: See [previous POZ coverage](#) of [earlier studies](#) of this vaccine approach.]

This Phase I study will evaluate dose levels via a dose escalation model in 96 adult participants at six clinical sites in South Africa. All participants are healthy adults living without HIV. This model is designed to identify the lowest dose of the immunogens that elicits an immune response, while minimizing the risk of side effects, particularly skin reactions like those observed in an earlier completed study, IAVI G002.

IAVI G004 builds on the promising results observed in the [IAVI G001, G002, and G003 clinical](#)

trials, which demonstrated proof of concept for a biological pathway to generate bnAbs against HIV.

“It is very exciting to see the launch of the IAVI G004 clinical trial,” said IAVI President and CEO Mark Feinberg, MD, PhD. “With this year’s global funding cuts to HIV prevention, care, and treatment, bringing new prevention tools forward is more important than ever. We believe we are on the most promising path ever pursued for the development of an effective vaccine against HIV. We are very grateful for the global network of partners whose contributions have enabled this trial to go forward.”

HIV remains a significant global public health threat. With over 40 million people living with HIV, and over a million people each year newly acquiring HIV, new tools for HIV prevention remain a pressing public health need. Development of an efficacious and safe HIV vaccine that can deliver long-lasting immunity is an urgently sought public health goal. Even with the advent of highly efficacious long-acting antiretroviral drugs for pre-exposure prophylaxis (PrEP), the availability of an efficacious HIV vaccine will likely be required to sustainably control and eventually end the AIDS pandemic.

The IAVI G004 clinical trial will be conducted by African investigators who will also lead the conduct of a detailed analysis of the immune responses elicited by the immunogens. The clinical research centers conducting the trial, all of which are in South Africa, are the Desmond Tutu Health Foundation (DTHF) Emavundleni and Groote Schuur Hospital Clinical Research Sites (J52) in Cape Town; the eThekweni CAPRISA Research Clinic in Durban; the South African Medical Research Council (SAMRC) Isipingo Clinical Research Center in Isipingo Rail; the Setshaba Research Centre in Soshanguve; and the Perinatal HIV Research Unit in Soweto.

The HIV immunogens being evaluated in this trial, eOD-GT8 60mer, Core-g28v2 60mer, and N332-GT5 gp151, were developed at Scripps Research in the laboratory of William Schief, PhD, professor at Scripps Research; vice president for protein design in infectious disease research at Moderna, Inc.; and executive director of vaccine design at IAVI’s Neutralizing Antibody Center; and evaluated by IAVI, Scripps Research, and other partners.

“We are excited to evaluate these mRNA immunogens at lower doses, including two immunogens previously tested at higher doses and the first-in-human test of our N332-GT5 membrane-bound trimer aiming to prime a new type of bnAb. We are hoping this study will demonstrate safety and immunogenicity and lead to future studies that induce protective bnAbs,” said Schief.

“Whilst there have been wonderful breakthroughs in pre-exposure prophylaxis in recent years, the need for a safe and effective vaccine to eliminate HIV infection remains as urgent as ever. The commencement of this important trial in South Africa where that need is so great moves us closer to the goal of ending HIV for everyone everywhere. I’m grateful to the IAVI and site research teams who have worked hard to be ready and the communities who are willing to participate,” said Linda-Gail Bekker, MBChB, DTMH, DCH, FCP (SA), PhD, CEO of the Desmond Tutu Health Foundation, IAVI Board of Directors member, and principal investigator for the study.

Funding for this clinical trial has been provided by the Gates Foundation through the Collaboration for AIDS Vaccine Discovery (CAVD), with funding for the clinical trial materials provided through the Scripps Research Center for HIV/AIDS Vaccine Development (CHAVD). Clinical trial materials were manufactured by Moderna. IAVI and Scripps Research scientists developed the vaccine candidate with funding from the Gates Foundation to the IAVI Neutralizing Antibody Center (NAC) under the CAVD. Research at the IAVI NAC that contributed to the development of the vaccine candidates was also made possible by the government of the Netherlands through the Minister of Foreign Trade & Development Cooperation.

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<http://beta.docker.realhealthmag.com/article/iavi-announces-first-vaccinations-phase-trial-promising-hiv-vaccine-approach>