

Phase 1 clinical trial of HIV vaccine starts in Africa to evaluate immune responses to highly networked HIV T-cell epitopes

Led by a team of African researchers, first doses of the novel T cell-inducing GRAdHIVNE1 vaccine candidate have been given.

Harare, Zimbabwe; Rome, Italy; New York, NY, and Cambridge, MA, USA, August 4, 2025 – The Mutala Trust, ReiThera Srl (ReiThera), the Ragon Institute of Mass General Brigham, MIT, and Harvard (the Ragon Institute), and IAVI are pleased to announce that the first doses of an investigational HIV vaccine candidate have been administered. The vaccine candidate, Gorilla Adenovirus Vectors HIV Networked Epitopes Vaccine (GRAdHIVNE1), was first administered on July 28, 2025, at the Mutala Trust clinical trial site in Harare, Zimbabwe. This effort is made possible by a global collaboration and a team of African principal investigators who will lead the clinical research in South Africa and Zimbabwe (listed below). Vaccine immunogenicity will also be assessed locally by a network of state-of-the-art African research institutes: Cape Town HVTN Immunology Laboratory in Cape Town, African Health Research Institute in Durban, and the National Institute for Communicable Diseases in Johannesburg, South Africa.

This Phase 1, first-in-human clinical trial will enroll approximately 120 healthy adults aged 18–50 years, including 48 people living with HIV who are virally suppressed on antiretroviral therapy (ART). The trial is designed to assess the safety and immunogenicity of the vaccine candidate in people living with and without HIV. Participants will receive either one or two doses of the investigational vaccine or a placebo and will be monitored over a period of 19 months for safety and immune responses.

This clinical trial, IAVI C114, is sponsored by IAVI. GRAdHIVNE1 has been made possible by a collaborative effort. ReiThera developed the GRAd viral vector platform and manufactured the vaccine candidate, while the Ragon Institute designed the immunogen using novel strategies to identify protective HIV epitopes and facilitate their targeting by T cells. This clinical program is funded by the Gates Foundation.

The IAVI C114 clinical trial is taking place at three clinical trial sites: the Mutala Trust Clinical Trial Site, in Harare, Zimbabwe; the Desmond Tutu Health Foundation (DTHF), in Cape Town, South Africa; and the Africa Health Research Institute (AHRI), in Durban, South Africa. To determine the vaccine candidate's potential for relevance in sub-Saharan Africa, where disease burden is greatest, it is essential that the candidate be tested within communities affected by the epidemic.

"This is a landmark moment for South Africa, Zimbabwe, and the continent. It shows the power of true partnership: IAVI's sponsorship, ReiThera's GRAd technology, the Ragon Institute's innovative immunogen built on decades of science, and African investigators co-leading every phase of the trial. We are edging closer to an HIV vaccine, made possible by global collaboration, with clinical trials conducted in Africa, for Africa, and for the world," said Dr. Tariro Makadzange, Clinical Trial Lead, Mutala Trust.

"This trial represents the future of vaccine development, rooted in Africa, built through global partnerships, and designed for the communities most affected by HIV," said Dr. Vincent Muturi-Kioi, HIV Vaccines Product Development Team Lead at IAVI.

The vaccine candidate is designed to engage the immune system to recognize and target critical structural regions of HIV using a clinically validated, potent, T cell-inducing GRAd vector. This approach will be evaluated to assess the ability of the vaccine candidate to direct strong CD8+ T cell immune responses towards these vulnerable viral regions.

"We are thrilled to be moving insights from our long-term studies of spontaneous elite controllers of HIV toward the development of GRAdHIVNE1 and its testing in Africa. We are truly grateful to the network of global and African partners that have come together to make the IAVI C114 trial a reality," said Dr. Gaurav Gaiha, Associate Professor of Medicine at Harvard Medical School and Principal Investigator at the Ragon Institute of Mass General Brigham, MIT, and Harvard.

Because CD8+ T cells induced by this vaccine hold promise for targeting HIV-infected cells, this clinical trial will also assess the safety and immune response in people living with HIV. These data will be used to assess the suitability of the vaccine candidate for the development of investigational HIV therapeutic and curative interventions.

“We are enormously pleased with the launch of this Phase 1 trial representing the result of a successful global partnership,” said Stefano Colloca, CEO and co-Founder of ReiThera. “This candidate HIV vaccine, built on our GRAd platform, holds great promise to trigger a strong CD8 response targeting vulnerable viral regions.”

Principal Investigators Leading Clinical Trial Sites:

- Tariro Makadzange, Mutala Trust
- Theodorah Rirhandzu Ndzhukule, DTHF
- Limakatso Lebina, AHRI

About IAVI

IAVI is a global nonprofit scientific organization that works to develop vaccines and antibodies to prevent HIV and other infectious diseases, with a focus on innovation and equitable access. IAVI is the sponsor of this trial. Read more at www.iavi.org.

About Mutala Trust

Mutala Trust is founding member of Africa Clinical Research Network (ACRN) and is a site based in Harare, Zimbabwe. It is known for conducting high-quality, ethically sound clinical trials addressing diseases that affect African communities. Mutala is the clinical lead site for the study.

About ReiThera Srl.

ReiThera Srl, an Italian CDMO specializing in technology and process development as well as GMP manufacturing of viral vectors for genetic vaccines and advanced therapies, is the developer and owner of the GRAd platform used for this HIV vaccine.

About the Ragon Institute of Mass General Brigham, MIT, and Harvard

The Ragon Institute of Mass General Brigham, MIT, and Harvard was established with a collaborative scientific mission among these institutions that brings scientists, clinicians and engineers together to harness the immune system to combat and cure human disease. They contributed to vaccine design. For more information, visit www.ragoninstitute.org