## Experimental mRNA-based Preventive HIV Vaccine Phase 1 Trials March 2022

Trial	IAVI G002	<u>HVTN 302</u>
Name	A Phase 1 Study to Evaluate the Safety and Immunogenicity of eOD-GT8 60mer mRNA Vaccine (mRNA-1644) and Core- g28v2 60mer mRNA Vaccine (mRNA- 1644v2-Core	A Clinical Trial to Evaluate the Safety and Immunogenicity of BG505 MD39.3, BG505 MD39.3 gp151, and BG505 MD39.3 gp151 CD4KO HIV Trimer mRNA Vaccines in Healthy, HIV-uninfected Adult Participants
Clinicaltrials.gov	<u>NCT05001373</u>	<u>NCT05217641</u>
Phase	1	1
Hypothesis	Sequential vaccination by a germline- targeting prime followed by directional boost immunogens can induce specific classes of B-cell responses and guide their early maturation toward broadly neutralizing antibody (bnAb) development through an mRNA platform	The BG505 MD39.3 soluble and membrane-bound trimer mRNA vaccines will be safe and well-tolerated among HIV-uninfected individuals and will elicit autologous neutralizing antibodies
Planned Dates	Nov 2021-Apr 2023	Feb 2022-Oct 2023
Sponsor	IAVI	NIAID/NIH
Funder	Bill & Melinda Gates Foundation	NIAID/NIH
Participants	56 adults ages 18 to 50 Years	108 adults ages 18 to 55 years
Trial Sites	4 sites in the US (Atlanta; San Antonio, Seattle; Washington, DC)	11 sites in the US (Birmingham; Boston; Los Angeles; New York City; Philadelphia; Pittsburgh; Rochester; Seattle)
Vaccine Candidates	<ul> <li>Two experimental HIV vaccines based on messenger RNA (mRNA) platform:</li> <li>1. eOD-GT8 60mer mRNA Vaccine (mRNA-1644)</li> <li>2. Core-g28v2 60mer mRNA Vaccine (mRNA-1644v2-Core)</li> </ul>	<ul> <li>Three experimental HIV vaccines based on messenger RNA (mRNA) platform:</li> <li>1. BG505 MD39.3 mRNA</li> <li>2. BG505 MD39.3 gp151 mRNA</li> <li>3. BG505 MD39.3 gp151 CD4KO mRNA</li> </ul>
Vaccine Manufacturer	Moderna	Moderna
Immunogen Design	IAVI Neutralizing Antibody Center (NAC) and Scripps Research	Scripps Consortium for HIV/AIDS Vaccine Development (CHAVD) and IAVI Neutralizing Antibody Center at Scripps
Press Release	IAVI and Moderna launch trial of HIV vaccine antigens delivered through mRNA technology, January 27, 2022	NIH Launches Clinical Trial of Three mRNA HIV Vaccines, March 14, 2022