

HVTN HIV Vaccine Trials Glossary

Adenovirus: a common virus that causes colds and sore throats. A defective adenovirus (one that cannot grow or cause adenovirus infections in humans) is sometimes used as a **vector** in HIV vaccines.

Adjuvant: a substance that may be included in a vaccine to improve the body's ability to fight disease or infection.

Adverse experience: a bad experience that may be related to receiving vaccine, such as fever, chills, rash, aches and pains, nausea, headache, dizziness, and fatigue.

Antibody: a protein in the body that can attach itself to a specific invading organism (e.g., virus) and tell the body to destroy it. Antibodies destroy the invader before it can infect or cause harm to the body's cells.

Antibody-mediated immunity: see **humoral immunity**

Antigen: a foreign substance (e.g., a virus) that enters the body and causes the body's **immune system** to respond.

Autoimmune disease: a disorder in which a person's immune system attacks parts of his or her own body

B cells: white blood cells that produce antibodies which are important to the body's defense against foreign invaders through **antibody** production.

Cellular immunity: protection provided by the cells of the body's immune system (as opposed to protection provided by **antibodies—humoral immunity**).

Clade: a subtype or strain of HIV. Different HIV clades exist in various regions of the world.

Clinical trial: a research study or experiment in humans (as opposed to animals) that is designed to answer specific questions.

Control: a substance or product included in a trial that is used to compare its effect to that of the vaccine being studied. The control may be an inactive substance (**placebo**) or some other vaccine product.

Cytotoxic T cells: see **killer T cells**

Data Safety Monitoring Board (DSMB): an independent group that reviews data during the study and can recommend a study to be stopped if it appears the volunteers are being placed at risk.

DNA vaccine: a vaccine that uses genes made of HIV desoxynucleic acid (DNA) to trigger an immune response. In HVTN trials, vaccines using this method use only SOME genes of HIV, not the whole virus. Receiving vaccine in an HVTN trial *cannot* infect a participant with HIV or AIDS.

Double-Blinded Study: a study in which neither the investigator nor the participant knows whether the participant is receiving a vaccine or a **control**. Double-blinded studies are designed to prevent bias when conducting the trial or analyzing the results.

Efficacy: the effectiveness of a vaccine, or how well a vaccine works.

Epitope: a specific part on the surface of a foreign invader (e.g., a virus) that is targeted for destruction by the body's **immune system**.

Helper T cells: a group of T cells help produce **antibodies**, activate **killer T cells**, and make sure the immune system works smoothly.

HLA (human leukocyte antigen): markers on the surface of a body's cell that identify the cell as one's own (as opposed to a foreign cell) and prevent the **immune system** from attacking itself.

Humoral immunity (antibody-mediated immunity): protection provided by **antibodies** (as opposed to **cellular immunity**, which is protection provided directly from immune cells).

Immune system: the body system, made up of many organs and cells, that defends the body against infection, disease, and foreign substances.

Immunogenicity: ability to protect against a infection, disease, and foreign substances.

Immunosuppressive: capable of disabling the body's ability to protect against infection or disease.

Inactivated vaccine (killed vaccine): a vaccine made from a whole virus or bacterium whose ability to grow or reproduce has been eliminated. The vaccines in HVTN trials do not contain inactivated or killed HIV virus. Receiving vaccine in an HVTN trial *cannot* infect a participant with HIV or AIDS.

Investigational vaccine: a vaccine that has been approved by the U.S. Food and Drug Administration (FDA) for experimental testing in humans, but has not yet been proven effective.

Informed consent: the process of deciding whether or not to join a clinical trial, after learning enough information to make a responsible decision about participating. All trial participants must provide written agreement before entering a study.

Injection: a shot.

IRB (Institutional Review Board): one of the groups that monitors HVTN trials. Each research institution (such as a university) has an IRB, that reviews studies to make sure they are scientifically and ethically acceptable to the participant.

Killer T cells (cytotoxic T cells, cytotoxic lymphocytes, CTLs): a group of T cells that is activated by **helper T cells** and have the ability to destroy cells infected by foreign invaders (e.g., viruses).

Live attenuated vaccine: a type of vaccine that uses a weakened version of an organism (e.g., the polio vaccine). The vaccines in HVTN trials do not contain live attenuated HIV virus. Receiving vaccine in an HVTN trial *cannot* infect a participant with HIV or AIDS.

Lymphocytes: blood cells, such as T cells and B cells, that are essential in immune defense.

Memory cell: a T or B cell that has been exposed to a specific invading organism and remembers the organism. Memory cells help the **immune system** respond faster when they encounter invading organisms for the second time.

Microbe: a tiny living organism, such as a bacterium or virus.

Mucosal membranes: moist (wet) tissues that line body cavities or passages that have an opening to the external world, such as the mouth, nose, rectum or vagina.

Mutation: a change in the genetic material (DNA) inside of a cell that results in a new characteristic. HIV is a virus that mutates frequently as it replicates, possibly resulting in a stronger and/or drug-resistant virus.

Phase I trial: an early clinical trial designed to study an experimental vaccine in humans. Phase I trials are generally small (less than 100 participants) and designed to see if the product is safe.

Phase II trial: an intermediate clinical trial for studying an experimental vaccine in humans. The goals of Phase II trials (hundreds of participants) are usually to learn more about vaccine safety and to see if the vaccine generates an immune response. Phase II trials occur only after the experimental vaccine is shown to be safe in a smaller **Phase I trial** (safety).

Phase III trial: an advanced clinical trial in humans (thousands of participants) designed to prove whether or not a vaccine is effective. Phase III trials occur only after the experimental vaccine has successfully moved from a **Phase I** (safety) and **Phase II trial** (safety and immune response).

Placebo: an inactive substance designed to resemble the vaccine (or treatment) being studied. Participants taking a placebo form the control group in blinded clinical trials.

Preclinical: testing of a vaccine or drug in cells or animals before testing in humans.

Principal Investigator: the scientist in charge of a research team conducting **clinical trials**.

Protocol: the plan for a research study.

Randomized: assigned to a group by chance, like the toss of a coin. What a participant receives (vaccine or **control**) will depend on which group he/she is in.

Recombinant vaccine: vaccine that uses genetic material from a disease-causing organism to produce an immune response. For instance, an HIV recombinant vector vaccine uses a vector (a weakened virus or bacterium) to transport genetic material from man-made HIV proteins into the body. Receiving vaccine in an HIV trial *cannot* infect a participant with HIV or AIDS.

Screening: the process clinicians use to see if a volunteer is eligible to participate in a clinical trial. Screening usually includes a medical history, including personal questions and laboratory tests.

Side effect: a symptom that may occur when a participant receives an injection. See **adverse experience**.

Specimen: a bodily fluid (such as blood, urine, or semen) collected for the purpose of laboratory testing.

Subunit vaccine: a vaccine that uses one or more parts of a disease-causing organism, rather than the whole, to stimulate an immune response. The Hepatitis B vaccine is an example of a subunit vaccine. Receiving vaccine in an HVTN trial *cannot* infect a participant with HIV or AIDS.

Tolerability: the body's ability to support or withstand a vaccine or medicine.

Toxicity: the extent, quality, or degree of harm to the body.

Triad: A working union of the HVTN, the International AIDS Vaccine Initiative (IAVI), and the U.S. Military HIV Research Program (USMHRP)

Vector: a weakened bacterium or virus (other than HIV) used to carry some HIV genes into the body to create an immune response. In HVTN trials, vaccines using this method use only **SOME** genes of HIV, not the whole virus. Receiving vaccine in an HVTN trial *cannot* infect a participant with HIV or AIDS. (See **recombinant vector vaccine**.)