



# Glossary

Community Advisory Board  
Guide to HIV Clinical Research



This glossary was developed for the purpose of supporting members of the IMPAACT Community Advisory Board (CAB) in their work. The words defined here and the acronyms included are those that are commonly used in the research network and in clinical trial protocols. Many of the words in the glossary are defined here because they are included in the IMPAACT Training Curriculum for Community Advisory Boards.

Terms and acronyms are listed in alphabetical order. Some words used in the definitions of terms are *italicized*. The *italics* indicate that the word is defined elsewhere within the glossary.

This tool was developed by the François-Xavier Bagnoud Center at the University of Medicine and Dentistry of New Jersey (UMDNJ), with the support of the International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT). Sources for some definitions are listed at the end of this booklet.

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# Glossary

*of Commonly Used Words in HIV Clinical Research*

## A

**Accrual:** The build-up or increase in the number of participants in a clinical trial

**Acquired immunodeficiency syndrome (AIDS):** Final and most severe stage of disease due to infection with the human immunodeficiency virus (HIV)

**Activism:** The practice of taking direct action in support of or in opposition to a specific issue or cause

**Activist:** An advocate. (See *Advocate*) A person who engages in activism

**Acute HIV infection:** (Also known as primary HIV infection). The period of rapid HIV replication (increasing amount of virus in the body) that occurs shortly after becoming infected with HIV

**Adherence:** Taking the correct dose of a medicine at the correct time

**Adjuvant:** A substance added to a medicine that improves the original medicine. For example, adding aspirin or acetaminophen to a narcotic pain reliever can boost the pain relief effect of the narcotic. Adjuvant also refers to a substance added to a vaccine to improve the body's immune response to that vaccine.

**Adverse event (AE)** (also known as side effect or adverse reaction): An unwanted symptom or medical problem caused by a medicine

**Advocate:** A person who supports a cause (an advocate of equal rights for women) OR one who speaks on behalf of another

person (an advocate for people who are *HIV-infected*)

**Affiliated:** Associated with or a part of

**Adult AIDS Clinical Trials Group:** US funded research network dedicated to reducing illness and death among HIV-infected adults

**Analyze:** To study data (information) to determine clinical trial results

**Anonymous:** Nameless or unidentified

**Antenatal** (See *Prenatal*): Before birth

**Antibody:** A protein produced by the immune system that recognizes and fights infectious organisms that enter the body. Each antibody is specific to a particular infectious organism (such as HIV antibodies or measles antibodies).

**Antigen:** Any substance that can stimulate the body to produce antibodies (Example: HIV can be an antigen).

**Antiretroviral (ARV):** An anti-HIV medicine (See *Antiretroviral therapy*)

**Antiretroviral therapy (ART):** Course of treatment with anti-HIV medicine or medicines

**Arm:** The treatment or placebo group in a clinical trial may be referred to as an "arm" of the study.

**Asymptomatic:** Having no signs or symptoms of disease

## B

**Barrier:** Something that prevents or blocks an action or activity

**Baseline data:** Information gathered about the participant before study treatment begins. To study the effect of a treatment, baseline information is compared with information gathered later in the trial.

**Benefit:** A good, positive, or useful effect

**Bias:** Unfair favoring or unfair judgment. A point of view that is not impartial

**Blinded or double-blinded study:**

Neither the participants nor the investigators know to which group a participant is assigned

## C

**CD4 cell** (also known as T-cell): A type of white blood cell in the immune system that helps protect the body from infections. HIV destroys CD4 cells, harming the immune system of the body and leaving the person at higher risk of serious infection or disease.

**CD4 cell count:** An indirect way to measure how much damage has been done to the immune system by HIV

**CD4 percentage:** The percentage of white blood cells in the immune system that are CD4 cells. CD4 percentage is a more stable marker of immune system status than the CD4 count.

**CD8 cell:** A type of white blood cell in the immune system that stops antibody production and other immune responses

**Capsule:** In the context of a proposal for a clinical trial, a capsule is a brief outline of a proposed study.

**Case report:** The record that tells something unusual about what has happened with a patient. Case reports led doctors to identify AIDS and later, HIV.

**Case report form (CRF):** Forms used to collect clinical trial data

**Centers for Disease Control (CDC):** A US agency responsible for promoting health by preventing and controlling disease, injury, and disability

**Cerebral spinal fluid (CSF):** Fluid that bathes the spinal cord and brain. Samples of this fluid can be removed for laboratory studies, for example, measuring the amount of HIV in the CSF, or to check the fluid for signs of infection.

**Class (of medicine):** A group of medicines that work in the same way to treat a disease or health problem. There are 5 classes of anti-HIV medicines.

**Clinical endpoint:** In a research trial, a clinical endpoint refers to a disease, symptom, or sign that is one of the indicators of whether or not a treatment is safe and effective. For example, a clinical trial investigating the ability of a medication to prevent heart attack might use chest pain as a clinical endpoint.

**Clinical failure:** The occurrence or recurrence of HIV-related infections or a decline in physical health despite taking anti-HIV medicines. Clinical failure may occur because of immunologic or virologic failure. (See *Immunologic failure*, *Virologic failure*.)

**Clinical study:** Research involving people (See *Clinical trial*)

**Clinical trial:** A research study that involves people. Clinical trials are the fastest and safest way to find effective, safe treatment for a disease, condition, or symptom.

**Clinical trials network (CTN):** A group of hospitals and clinics in different locations that cooperate to develop and conduct clinical trials related to preventing or treating a specific health problem. Participants from many different locations may enter the same clinical trial, and researchers from many different locations can work together to advance knowledge and improve health care.

**Clinical trials specialist (CTS):** Person at the clinical trials *operations center* who manages protocol development, including all communications and coordination among the research team, sponsors, and regulatory agencies

**Clinical trials unit (CTU):** A research site that is part of a *clinical trials network*. A CTU conducts clinical research, and may contribute expertise to developing research in cooperation with other experts in the network.

**Co-enrollment:** Participating in more than one clinical trial at the same time

**Cohort:** A group of participants in a clinical trial who are grouped according to a common health factor (such as prior *ART* experience)

**Collaboration:** Working together toward a shared goal.

**Community:** A group of people with mutual concerns living in a particular area or belonging to the same group

**Community advisory board (CAB):** A CAB is a group of individuals representing the community where the research is being conducted. The members of the CAB are responsible for encouraging communication between the community and the research scientists. CAB members educate the

community about research in general and about specific clinical trials being proposed or being conducted in the network. CAB members inform researchers about the needs of the community and the concerns of the community, and they give feedback to the researchers from the community about issues related to the network's research plans.

**Community assessment:** Determining the current level of knowledge and the learning needs of a community

**Community Partners:** A committee formed to promote effective representation of and timely communication among the many communities, in the US and internationally, within which the *DAIDS*-sponsored Clinical Trials Networks conduct research.

**Community based organization (CBO):** A service organization in the community. For example, a nonprofit organization providing free counseling or other social services to people with HIV in the local community is a CBO.

**Comparison trial:** In most comparison clinical trials, one group of participants receives the experimental medicine while another group of participants receives the standard treatment. "Standard" refers to the medicine patients who are not participating in the clinical trial usually receive as treatment for the health problem being studied. The group of participants receiving standard treatment is called the "*control group*".

**Compassionate use:** Term used to describe any program that provides an experimental medicine outside of clinical trials to patients who do not have other treatment options

**Complication:** A problem resulting from the disease or its treatment

**Concept sheet (CS):** A brief proposal for a research study or clinical trial

**Confidentiality:** Keeping personal information private. Personal information collected during a clinical trial is not recorded or transmitted by name, date of birth, or other types of personal information.

**Confounding factor:** Any characteristic other than the treatment that might affect the results of a clinical trial.

**Control group:** In most comparison clinical trials, one group of participants receives the experimental medicine while another group of participants receives the standard treatment. Standard refers to the medicine patients who are not participating in the clinical trial usually receive as treatment for the health problem being studied. The group of participants receiving standard treatment is called the control group.

**Controlled clinical trial:** A clinical trial in which one group of participants is given the experimental medicine (*investigational group*) and compared with a group of participants given standard treatment (*control group*).

**Counselling:** The confidential discussion between an individual and a health service provider

**Criteria:** A standard by which something may be judged. For example, one of the criteria used to measure the success of anti-HIV treatment is the *viral load*.

**Cross-Network community advisory board (CAB):** See *Community Partners*

**Cross-resistance:** Occurs when HIV has changed (mutated) in such a way that

it gains the ability to live and reproduce despite the presence of anti-HIV medicine. In addition, the mutation creates the ability for the virus to live and reproduce in the presence of similar anti-HIV medicines. For example, resistance to one drug in a class, e.g. an NNRTI, usually produces resistance to all drugs in that class, i.e. resistance to all NNRTIs.

## D

**Data:** Information collected during a *clinical trial*

**Data analysis:** Studying the information collected during a clinical trial to determine the results of the trial

**Data analysis concept sheet (DACS):** A *proposal* to analyze data from existing *protocol(s)* to address a specific scientific question

**Data manager:** A person who specializes in organizing and maintaining the *data* collected during clinical trials

**Data Management Center (DMC):** The administrative center supporting the collection and organization of *data* from *clinical trials*. The *IMPAACT data management Center is Frontier Science and Technology Research Foundation (FSTRF)*

**Data Safety and Monitoring Board (DSMB):** An independent committee composed of clinical research experts. They review information while a clinical trial is in progress, to see if there are safety risks and to see if the study *objective* has been reached. A DSMB may recommend that a trial be stopped if there are safety concerns or if the investigational medicine proves to be as or more effective than *standard treatment*.

**Disclosure:** Informing another person or persons of one's HIV infection status

**Discordant couple:** A pair of sex partners, one of whom is HIV-infected and the other is not

**Discrimination:** Unfair treatment of a person or group based on prejudice

**Division of Acquired Immunodeficiency Syndrome (DAIDS):** A US Government-funded division of the National Institute of Allergy and Infectious Disease. DAIDS was created in 1986 to address the research needs related to HIV infection.

**Dose-ranging study:** A clinical trial in which two or more doses of the same medicine are tested against each other to determine which dose works best and is least harmful

**Double-blind study:** A type of clinical trial where neither the participant nor the researcher knows which treatment a participant is receiving

**Drug-drug interaction:** An unexpected or unwanted effect of a medicine when given with another medicine

**Drug holiday:** (See *Structured treatment interruption*): When a person stops taking antiretroviral treatment for a period of time, under medical supervision

**Drug resistance:** The ability of a virus like HIV (or bacteria) to change so that it can continue to reproduce, even in the presence of medicines that would normally kill it

**Duration:** Length of time

## E

**Effective:** Useful. Having a positive effect on a condition or disease

**Efficacy:** Usefulness in treating or preventing a medical problem

**Eligibility criteria** (See *inclusion and exclusion criteria*): The general characteristics (like age or sex) and specific characteristics (like viral load or prior HIV treatment) that are required to join a clinical trial

**ELISA/Western Blot** (See *HIV-antibody test*): The blood tests used to determine presence or absence of HIV antibodies in the blood

**Empirical:** Proven. Based on experimental data, not on theory

**Endpoint:** A measurable change in the condition of a person in a clinical trial that is used to determine whether a therapy is effective. (See *Clinical endpoint*.) A laboratory endpoint refers to something that can be measured by another blood test (such as a *viral load test*) or other type of laboratory test.

**Enroll:** To enter a clinical trial as a participant

**Epidemiology:** The study of when, where, why, and how a disease occurs in a population

**Ethical:** Fair, right, or just

**Ethics Committee:** (See *Institutional Review Board or IRB*): The committee of people who must give approval before a clinical trial is permitted to begin. Each *clinical trials unit* must obtain permission from the Ethics Committee (or *IRB*). This committee also monitors the clinical trial while it is ongoing to watch for unexpected safety issues, issues related to the rights of participants, and to the *ethical* behavior of individual researchers and the research team.

**Evaluations:** The tests or examinations done during the course of a clinical trial to check the health status of participants

**Evidence-based health care:** Providing care guided by the results of clinical research

**Exclusion criteria:** The characteristics that disqualify a volunteer from enrolling in a particular clinical trial

**Exclusive breastfeeding:** Providing nourishment for an infant with breastmilk only (no water, formula, or other source of nourishment is given).

**Expanded access:** A program to make an experimental medicine available to people who do not qualify for the clinical trial

**Expedited adverse event (EAE):** An adverse event that must be reported quickly to DAIDS as defined in the protocol

**Experimental drug/medicine:** A medicine that has not been approved and licensed for use in humans

## F

**Field representative:** A member of the research team responsible for evaluating a *protocol* during development to determine if the requirements of the study can be reasonably managed at a *clinical trials unit (CTU)*. Usually an experienced study coordinator, research nurse, research assistant, or data manager from a CTU.

**First-line treatment** (See *First-line regimen*): The first group of *ARV* medicines to be used as treatment for HIV in an individual

**Fixed-dose combination (FDC):** A capsule or tablet containing doses of two or more medicines

**Follow up:** Further action that results from and is intended to add to something that was done earlier

**Food and Drug Administration (FDA):** The agency responsible for ensuring the safety and effectiveness of medicines, vaccines, and medical devices licensed in the US

**Formulation:** The physical form in which a medicine is taken, such as tablets, capsules, or liquids

**François-Xavier Bagnoud (FXB) Center:** FXB provides clinical care, education, and technical assistance in the US and globally to support capacity building for addressing the HIV epidemic. FXB directs clinical research training programs for international CTUs associated with the *PACTG* and *IMPACT*.

**Fusion inhibitors:** A class of anti-HIV medicines that stops the fusing (sticking together) of HIV's outer envelope with the CD4 cell, thereby preventing infection of the CD4 cell (or T-cell) with HIV

## G

**Goal:** Something that a person or group wants to achieve; aim

**Good Clinical Practice (GCP):** A standard set of guidelines (procedures and rules) for the design; conduct; monitoring; recording, analysis, and reporting of results for clinical trials

## H

### **Highly Active Antiretroviral Therapy**

**(HAART):** Treatment for HIV infection using a combination of *ARVs* from at least two different classes

### **HIV: Human immunodeficiency virus:**

The virus that causes HIV infection and AIDS

**HIV-1:** Most common form of the virus

**HIV-2:** Another form of HIV that is less common than HIV-1. It is found primarily in West Africa and has a slower, less severe clinical course.

**HIV antibody test:** (See *ELISA/Western Blot*): The blood test used to determine presence or absence of HIV antibodies in the blood. A positive test result in anyone over 18 months of age indicates that the person is infected with HIV.

**HIV-exposed:** When a person was in the presence of HIV in a way that makes it possible the virus was transmitted to that person. For example, infants of HIV-infected mothers are HIV-exposed during pregnancy, labor and delivery, and during breastfeeding, so the infants are HIV-exposed and therefore at risk of becoming infected with HIV.

### **HIV Prevention Trials Network (HPTN):**

A DAIDS-funded clinical trials network that develops and tests the safety and usefulness of non-vaccine methods to prevent the spread of HIV from one person to another

### **HIV RNA PCR** (also known as *viral load*):

A blood test that measures the amount of HIV in the blood of an infected person. Viral load testing is one way to determine how well *ARVs* are working. Effective *ARV*

treatment can lower the viral load below the level that can be measured in the laboratory (undetectable viral load). If viral load increases while taking *ARVs*, it may indicate the medicine is not effective or is not being taken correctly.

### **HIV Vaccine Trials Network (HVTN):**

A DAIDS-funded clinical trials network that develops and tests vaccines to prevent or treat HIV

### **Horizontal transmission:**

HIV transmission from one person to another, except in the case of mother-to-child transmission (called *vertical transmission*)

### **Hypothesis:**

An unproven explanation used as a basis for a clinical trial. For example, a clinical trial comparing an experimental *ARV* to a *standard ARV* for *PMTCT* is based on the hypothesis that the experimental medicine will be as effective or more effective for reducing the risk of HIV transmission from mother to infant.

## I

### **Immune-based therapy (IBT):**

A therapeutic approach that aims to strengthen the immune response to HIV infection

### **Immune reconstitution syndrome (IRS):**

(Also known as *immune restoration disease (IRD)* or *immune reconstitution inflammatory syndrome (IRIS)*): An inflammatory reaction that may occur when a person's immune system improves after being very weak, such as when a person with AIDS begins anti-HIV treatment and experiences a rapid rise in *CD4 cell* count. Fever, together with swelling, redness, or pus at the site of an injury or infection may signal that an infection that was previously unnoticed

by a weak immune system is now being attacked by a stronger immune system. Although this indicates that a person's immune system has grown healthier, it can be a serious, sometimes fatal condition and must be treated. IRS does not signal HIV treatment failure.

**Immune response:** The body's defensive reaction to an "invader" such as a virus or bacteria

**Immunity:** Protection against or resistance to a disease

**Immunocompetent:** Able to mount a normal immune response to a virus or bacteria

**Immunocompromised** (See *Immunosuppressed*): Unable to mount a normal immune response

**Immunologic failure:** When an HIV-infected individual's *CD4 count* decreases below his or her baseline count, or does not increase above the *baseline* count despite anti-HIV treatment

**Immunosuppressed** (See *Immunocompromised*)

**Immunotherapy** (*also known as immune-based therapy or IBT*): Treatment to stimulate or strengthen the body's immune system to fight disease

**IMPAACT Community Advisory Board (ICAB):** A group of international community representatives made up of leaders from local and regional IMPAACT Community Advisory Boards (CABs)

**Incidence:** HIV incidence is the rate at which new cases of HIV occur in a population during a specified period of time. For example, the incidence of HIV in country X was 500/100,000 per year.

**Inclusion criteria:** The medical or social standards determining whether a person may be allowed to join a clinical trial.

**Informed consent:** The process of learning all of the key facts about a clinical trial before deciding whether to participate. The informed consent process continues throughout the study to provide information for participants, some of whom may decide to stop participating in the study at any time.

**Informed consent form:** A form that provides detailed written information about the clinical trial. Signing an informed consent form indicates that the person understands the information he or she has been given, and is voluntarily enrolling in the study. The form is not the same as signing a contract, because a participant may choose to stop participating in the trial at any time (withdraw from the trial).

**Infusion:** Administration of a solution into a vein

**Injection drug user (IDU):** Person who injects drugs for non-medical effects

**Institutional Review Board (IRB):** (See *Ethics Committee*): The committee of people who must give approval before a clinical trial is permitted to begin. Each clinical trials unit must obtain permission from the IRB (or *Ethics Committee*). This committee also monitors the clinical trial while it is ongoing to watch for unexpected safety issues, issues related to the rights of participants, and to the *ethical* behavior of individual researchers and the research team.

**Integrase inhibitors:** A class of anti-HIV medicines that prevent the HIV integrase protein from putting HIV information into the DNA (genetic material, genes) of an infected *CD4 cell*

**International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT):** A *DAIDS*-funded HIV research network. The mission of IMPAACT is to significantly decrease the *mortality* and *morbidity* associated with HIV disease in pregnant women, children, and adolescents.

**Intervention:** An action undertaken in order to change what is happening or might happen, especially to prevent something undesirable. For example, teaching the *ABCs* of HIV prevention is an intervention designed to reduce the risk of HIV transmission.

**Intrapartum:** The period of time including labor and delivery

**Intravenous:** Injection made directly into a vein

**Investigational group:** The group of participants receiving experimental medicine

**Investigational new drug (IND):** An experimental medicine being tested in a *clinical trial*

**Investigator:** Researcher

## J

**Justice:** Fairness

## L

**Latent:** Inactive

**Liaison:** Person serving as a link or connection between individuals or groups

## M

**Mentor:** A trusted counselor or guide

**Microbicide:** A substance used on the skin or membranes (such as in the vagina) to kill viruses or bacteria. In the case of HIV, a successful microbicide would be one that

would lower the risk of transmission of HIV from one person to another during sexual intercourse.

**Microbicide Trials Network (MTN):** A US-funded research network dedicated to the development of microbicides to reduce transmission of HIV

**Mission statement:** A document that describes the goal of a group, agency, or organization

**Monitor:** To watch, keep track of, or check (usually for a specific purpose)

- 1) Clinical trial participants are monitored closely for *adverse effects* of treatment.
- 2) Clinical trials units are monitored by outside professionals who ensure that research is conducted according to *Good Clinical Practice* guidelines and according to established government rules.

**Morbidity:** Illness

**Mortality:** Death

**Mother-to-child transmission (MTCT):**

Transmission of HIV infection from mother to infant during pregnancy, labor and delivery, or breastfeeding. Also called *vertical transmission*.

**Multiple drug-resistant (MDR):** An infection (such as HIV) that has genetically altered from its original state and become untreatable by medicines that used to be able to treat it effectively

**Mutation:** A adaptive change in HIV that can be passed down to new copies of HIV. If HIV replication (making of new virus) is not well-controlled (virus is very active and viral load is high), a mutation can occur so that the HIV can make an adaptive change and become *resistant* to anti-HIV medicines.

**Myth:** A popular belief or tradition about something or someone

## N

**Natural history study:** Study of the natural development (progression) of a disease over time. The term “natural” indicates that no intervention to prevent or stop the disease is provided during the study. Natural history studies of HIV disease are no longer *ethical* because *effective* treatment for HIV exists. (HIV-related clinical studies must include anti-HIV treatment when treatment is needed.)

**National Institute of Allergy and Infectious Diseases (NIAID):** US government-funded agency responsible for conducting and supporting research to better understand, treat, and prevent infectious, immunologic, and allergic diseases.

**National Institute of Child Health and Human Development (NICHD):** US government-funded agency with the mission of making sure that every child is born healthy and wanted, that women suffer no harmful effects from childbearing, and that all children have the chance to achieve the healthiest and most productive life possible.

**National Institutes of Health (NIH):** A multi-institute US government agency that is the center for US government-funded health research. It conducts research in its own laboratories and supports research in universities, medical schools, hospitals, and other research institutions in the US and at international sites.

**National Institute of Mental Health (NIMH):** US government-funded research

institute whose mission is to reduce the burden of mental and behavioral illness through research

**Network** (See *Clinical Trials Network*): A group of hospitals and clinics in different locations that cooperate to develop and conduct *clinical trials* related to a specific health problem. Participants from many different locations may enter the same clinical trial, and researchers from many different locations can work together to advance knowledge and improve health care.

**Network Executive Committee (NEC):** Group of *investigators* who represent the leadership of the research *network* and oversee the scientific agenda and its implementation

**Neutral:** See *Non-directive*.

**Non-adherence:** The failure or inability of a person to take medicines exactly as prescribed.

**Non-directive:** Providing accurate and complete information without trying to influence the individual’s decision

**Non-nucleoside reverse transcriptase inhibitors (NNRTIs):** A major category of anti-HIV medicine. Reverse transcriptase is required so that HIV can infect cells in the body and make more HIV. NNRTIs stop the reverse transcriptase from working properly. Examples of NNRTIs are delavirdine (DLV), efavirenz (EFV), and nevirapine (NVP).

**Nucleoside reverse transcriptase inhibitors (NRTIs):** A major category of anti-HIV medicine. This category of anti-HIV medicine prevents production of new HIV in a way similar to NNRTIs, but uses a different substance. Examples of NRTIs include abacavir (ABC), didanosine (ddl), lamivudine (3TC), stavudine (d4T), zalcitabine (ddC),

and zidovudine (ZDV or AZT).

**Nucleotide reverse transcriptase inhibitors (NRTIs):** This is a category of anti-HIV medicines based on nucleotides, which are chemically altered to stop the activity of a certain protein necessary for producing HIV. Examples of NRTIs include adefovir dipivoxil (ADV) and tenofovir (TDF).

**Nuremberg code:** A document that is used internationally to guide the ethical conduct of clinical research.

## O

**Objectives:** Measurable goals

**Observational trial:** A clinical trial in which no experimental treatment is provided. Participants are observed and health *data* recorded over a period of time.

**Open-label trial:** Not *blinded*. The investigator and the participant know which medicine the participant is receiving.

**Operations Center (OPS Center):** The administrative center for a *clinical trials network*, where the staff is responsible for coordinating, administering, tracking, documenting, and supporting all research activities of the network.

**Opportunistic infection (OI):** An illness caused by various germs, some of which would not usually cause disease in people with healthy immune systems. People living with advanced HIV infection have damaged immune systems, creating the opportunity for diseases to develop that would normally be preventable.

## P

**Parent-to-child transmission (PTCT):** A term preferred in some countries

(as opposed to MTCT, or mother-to-child transmission) because it places responsibility for the child's welfare on both parents, rather than solely on the mother.

**Participant** (also known as *subject*): A volunteer enrolled in a clinical trial

**Patient identification number (PID):** The number assigned to a participant in a clinical trial in order to maintain the confidentiality (privacy) of the personal information collected during the trial (*data*) Information about the participant is identified by a number, rather than by name.

**Pediatric AIDS Clinical Trials Group (PACTG):** *DAIDS*-funded HIV research network that studies treatments for HIV-infected children and adolescents and interventions for preventing mother-to-child transmission of HIV. In 2006, the PACTG joined with part of the *HPTN* to become the International Maternal, Pediatric, and Adolescent Clinical Trials (IMPAACT) group.

**Peer:** A person with a similar background or similar characteristics

**Peer educator:** A person who provides information and training to a person with a similar background or characteristics (e.g., adolescent-to-adolescent or HIV-infected mother to HIV-infected mother)

**Peer review:** Review of a clinical trial by experts not involved in the trial. These experts review the trial for scientific merit, participant safety, and ethical considerations.

**Performance Evaluation Resource Committee (PERC):** The *IMPAACT* committee responsible for oversight of the performance of individual Clinical Trials Units (CTUs)

**Perinatal:** Around the time of pregnancy, birth, and breastfeeding

**Pharmacokinetics (PK):** A test to find out the amount of medicine in the blood. This blood test shows how a medicine is absorbed and distributed in the body after it is taken.

**Phases:** Stages of clinical trials

**Phase I trial:** Testing medicine for safety and for the effective dose in a small number (10–100) of healthy people

**Phase II trial:** Testing medicine for safety in a larger number of people (50–500) who have the disease or symptom the medicine is intended to treat

**Phase III trial:** Testing medicine in large number of people (hundreds or thousands) with the disease or symptom the medicine is intended to treat, in order to determine if the medicine is effective and safe

**Phase IV trials:** Clinical studies conducted after a medicine has already been approved and licensed. A Phase IV trial determines the safety and effectiveness of an approved treatment over a long period of time. While Phase III trials are usually not longer than 2–3 years, Phase IV trials may be conducted for 5–10 years or more.

**Pill burden:** Refers to the number and schedule of pills or tablets taken each day in a particular anti-HIV regimen. A high pill burden may lead to decreased treatment *adherence* because of the difficulty of taking a large number of pills properly.

**Pill count:** A method for measuring *adherence* to ART that involves counting the number of pills taken and comparing that number against how many pills would have been taken if the patient had been adherent to the prescribed regimen.

**Placebo:** A pill that looks like the experimental medicine, but contains no medicine

**Placebo-controlled study:** A study in which the control group receives a placebo. See *Placebo*.

**Placebo effect:** A physical or emotional change, occurring after a substance is taken, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

**Placebo group:** The group of participants in a clinical trial assigned to receive a *placebo* rather than the experimental medicine

**Population:** A group of people who have a neighborhood, town, region, country, or quality in common. In research, a population to be studied in a clinical trial is a group of people who share specific health qualities (such as HIV infection).

**Post-exposure prophylaxis (PEP):** Anti-HIV medicine given to help prevent HIV infection after a high-risk exposure to HIV (such as injury from a contaminated needle, or sexual assault)

**Postnatal:** After birth

**Postpartum:** After birth

**Post-marketing studies:** (See *Phase IV trials*) Trials conducted after a new drug is approved and is being prescribed

**Prenatal** (See *Antenatal*): Before birth

**Prevalence:** Refers to the proportion of the population affected by a disease at a particular point in time (like a camera snapshot). For example, in 2003, 25% of the adults in country Y were HIV-infected.

**Prevention of mother-to-child**

**transmission (PMTCT):** Intervention to stop the passing of HIV from an infected mother to her infant during pregnancy, labor and delivery, or breastfeeding

**Prevention trials:** Clinical trials to find better ways to prevent disease (such as HIV) in people who have never had the disease. Approaches may include medicines, *vaccines*, or behavior change

**Preventive HIV vaccine:** A *vaccine* designed to prevent HIV infection in people who are not HIV-infected

**Principal investigator (PI):** The lead researcher for a particular clinical trial or the researcher in charge of all research at a *clinical trials unit*

**Prioritize:** Order things according to their importance

**Prognosis:** The prediction of recovery (or no recovery) based on the usual course of a disease and/or the likelihood that treatment of the disease will be effective

**Prophylaxis:** Treatment to prevent a particular disease or to prevent recurrence of an ongoing infection that has been brought under control

**Prospective studies:** This type of study looks forward in time. For example, a researcher selects a group of participants and observes the effects of a treatment on them for 6 months.

**Protease inhibitors (PIs):** A major category of anti-HIV medicines that block the action of the enzyme protease, which is needed for the virus to make more HIV. Examples of PIs include amprenavir (APV), atazanavir (ATV), indinavir (IDV), lopinavir (LPV), lopinavir/ritonavir (LPV/r), nelfinavir (NFV), saquinavir (SQV) and saquinavir soft-

gelatin capsule (SQV-sgc).

**Protease-sparing regimen:** An anti-HIV medicine regimen that does not include a medicine from the *protease-inhibitor* class

**Protocol:** A study plan. The study plan is designed to protect the health of participants and to answer specific research questions. A protocol describes what types of people may participate in the trial, the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of the treatment.

**Psychosocial:** Involving both mental and social aspects

**Q**

**Quality assurance (QA):** The planned system of actions established to ensure that a research study is performed in agreement with *Good Clinical Practice* guidelines and regulatory (legal) requirements

**R**

**Randomization:** Computerized assignment by chance to the investigational (experimental) or the control (*standard of care* or *placebo*) group

**Randomized clinical trial:** A study in which participants are *randomly* assigned to one of two or more treatment *arms* of a clinical trial

**Rapid test:** A type of HIV antibody test that can detect antibodies to HIV in the blood in fewer than 30 minutes with higher than 99% accuracy

**Rate:** Amount of change relative to *baseline*. For example, the rate of *virologic failure* in the investigational group of a clinical trial vs. the rate of virologic failure in the *control group* after 24 weeks of treatment

**Regimen:** In the medical context, a regimen is a combination of medicines prescribed to treat a condition or disease

**Regional Community Advisory Board (RCAB):** A committee of representatives from *CABs* in a geographical region (such as sub-Saharan Africa or western United States), who meet to discuss community issues related to research and HIV that are common among the *CTUs* in the region

**Researcher:** A scientist who helps to develop, manage, and analyze results of a clinical trial

**Research network:** See *Clinical trials network*.

**Resistance:** Term to describe the ability of HIV to change its structure so that an *ARV* medicine becomes less effective. The development of resistance to one *ARV* often means resistance to all *ARV* medicines within that class of *ARVs*. Resistance may develop as a result of non-*adherence* to the regimen prescribed.

**Resistance testing:** A laboratory test to determine if an individual's HIV strain is *resistant* to any anti-HIV medicines

**Retain:** To keep someone committed to being a member of a group

**Recruit:** To enroll or enlist someone, as in a clinical trial

**Risk:** The possibility of suffering harm or loss; danger

**Risk-benefit ratio:** The concept of considering the risk to individual participants in a clinical trial compared with the potential benefits

## S

**Safer sex:** Includes sexual practices that reduce the risk of exposure to HIV or other sexually-transmitted infections

**Safety:** Limiting exposure to potentially harmful effects of a treatment

**Salvage therapy:** Anti-HIV treatment regimen for people who have used many different anti-HIV medicines in the past, have failed at least two anti-HIV regimens, and have extensive *resistance* to anti-HIV medicines

**Sample** (also known as study sample): In the context of clinical trials, a study sample is the group of participants who are an example of the population being studied.

**Schedule of evaluations** (also known as schedule of events): The required schedule for a study participant during a clinical trial. Includes clinic visits, physical examinations, blood, and other testing to monitor health status

**Schema:** Outline of the design of a *protocol*, including *objectives* of the study, *randomization*, number of subjects, treatment arms, and criteria for treatment response and *treatment failure*.

**Scientific misconduct:** When a researcher does not follow the rules of ethical research. Examples: lying, making up data, stealing the work of other researchers

**Scientific Oversight Committee (SOC):**

*IMPAACT* clinical trial network leadership committee that monitors the scientific agenda of the network

**Screen/screening:** Tests and examinations required to check whether a volunteer is eligible to participate in the clinical trial. To check if a volunteer meets the *eligibility* requirements of the study

**Second-line treatment:** A regimen of *ARV* medicine prescribed for individuals who have developed *resistance* to a first-line *ARV* regimen, or who have experienced *treatment failure*.

**Seroconversion:** The process by which a newly-infected person develops antibodies to HIV

**Side effects** (See *Adverse effects*.): Unintended effects of a medicine

**Site monitor:** A person who evaluates the work of a *clinical trials* unit to ensure *Good Clinical Practice* rules, standard operating procedures, and regulatory (legal) requirements are followed

**Social and Scientific Systems (SSS):** Home of the Operations Center for *IMPAACT* and the *Adult AIDS Clinical Trials Group*

**Source documentation:** Written evidence showing that *data* reported in a clinical trial are accurate and true. For example, a laboratory report may serve as source documentation showing a *viral load* test was done on a subject on the date reported, and that the result is the same as the result reported for the study.

**Sponsor:** The organization, agency, or group that provides the money for a study

**Stakeholder:** A person or group with a direct interest or involvement in something

**Standard of care** (See *Standard treatment*.): A treatment plan that experts agree is appropriate, accepted, and widely used for a given disease or condition

**Standard operating procedure (SOP):** Written documents that describe in detail how a procedure should be done

**Standard treatment** (See *Standard of care*.): Treatment for a disease or condition that you would receive if not enrolled in a clinical trial. Approved treatment

**Statistical significance:** The probability that a difference in results between the *experimental* and *standard* treatment group occurred because of a treatment or intervention rather than by chance alone. In *clinical trials*, the level of statistical significance depends on the number of participants studied and observations made, as well as the size of the differences observed.

**Statistician:** A scientific specialist responsible for *analyzing* all of the data collected in a *clinical trial* to determine trial results. Statisticians are part of the *protocol* team, and are important in designing *clinical trials*. Statisticians ensure that the *study design* is appropriate for answering the research question being studied.

**Stigma:** A mark or token of disgrace

**Stratify:** To form into groups based on specific health indicators (such as *CD4 count*)

**Structured treatment interruption (STI)** (See *Drug holiday*.): A planned, medically-supervised discontinuation of anti-HIV medicines for a specific period of time

**Study coordinator:** A member of the research team at a *CTU*, who is responsible

for the day-to-day management of participants, the collection and recording of *data*, the development of *quality assurance* programs, communications with the *IRB* or ethics committee, and reporting to the principal investigator.

**Study design:** The type of investigative technique used in a clinical trial *protocol*. Includes descriptors such as *observational*, *double-blind*, *placebo-controlled*, and *randomized*

**Study objectives** (See *Objectives*): Goals of the clinical trial

**Study sample:** See *Sample*.

**Study team:** The principal investigator along with the other experts (such as the community representative) and staff who are conducting the clinical trial

**Subject:** Another name for a participant in a clinical trial whose reactions or responses to a treatment are studied

**Support group:** A group of people who meet to discuss personal issues related to a condition that affects them, with the purpose of creating psychosocial support (help)

**Susceptible:** In the context of HIV, this term is used to describe an HIV strain that is not resistant to a particular anti-HIV medicine. Also refers to having little *resistance* to a specific infectious disease

**Syndrome:** A set of symptoms or conditions that occur together and suggest a certain disease or an increased chance of developing a disease

**Systemic:** A word used to describe a disease or treatment that affects the body as a whole

## T

**Tanner staging:** A system for determining an adolescent's stage of sexual development. In HIV treatment, Tanner staging is used to determine the appropriate treatment guidelines to follow (adult, adolescent, or pediatric).

**T-cell** (also known as a *CD4 cell* or *CD4 lymphocyte*): A type of white blood cell in the immune system that helps to protect the body from infections. Destruction of *CD4 cells* by HIV harms the immune system, which leaves the person at higher risk of serious infection or disease.

**Teratogenic:** Causing harm to a fetus by interfering with normal *prenatal* development

**Therapeutic HIV vaccine:** An HIV *vaccine* used for the treatment of an HIV-infected person. Therapeutic HIV vaccines are made to boost the immune response to HIV infection, in order to better control the virus.

**Tolerability:** To indicate how well people react to a particular medicine when they take it at the usual dosages. Good tolerability means that the *side effects* do not cause people to stop using the medicine.

**Toxicity:** Ability to poison or otherwise harm the body

**Treatment-experienced:** HIV-infected individuals who are currently being treated with anti-HIV medicine or who have taken anti-HIV medicine in the past

**Treatment failure:** Failure of an anti-HIV treatment regimen to control HIV infection

**Treatment group:** The group of participants who are receiving the medicine being studied; the opposite of *placebo* group

**Treatment naïve:** A person who has never taken anti-HIV medicine

**Treatment trial:** A trial that tests new treatments or new combinations of medicine

## U

**Unblind:** Participants and/or researchers are given information regarding specific treatment assignments for participants who were previously “blinded” (not known)

**Undetectable viral load:** A *viral load* test result showing that the amount of virus in the blood sample is too low to be detected by the laboratory. An undetectable viral load usually shows that treatment is effective and/or that the person is at low risk of disease progression or of developing *resistance* to any ARV medicines being taken.

**Unprotected sex:** Sexual intercourse without the use of a condom

## V

**Vaccine:** A substance that stimulates the body’s immune response to prevent or control an infection. A vaccine is typically made up of some part of a bacteria or virus that cannot itself cause an infection. Researchers are testing vaccines to both prevent and treat HIV.

**Valid:** An unbiased assessment

**Verification:** Confirmation or proof

**Vertical transmission:** Transmission of HIV from mother to infant during pregnancy, labor and delivery, or breastfeeding

**Viral load (VL):** The amount of HIV in the blood. Viral load can indicate the level of HIV activity, and can indicate whether the *ARVs* are effective. *Viral load* is lowered by effective ARV treatment.

**Virologic failure** (See *Treatment failure*): Inability of anti-HIV medicine regimen to reduce *viral load* or to maintain suppression of viral load

**Virologist:** A scientist, usually a medical doctor, who specializes in the study of viruses

**Voluntary:** Coming from a person’s choice instead of from pressure from others

**Voluntary counselling and testing**

**(VCT):** Refers to *counselling* an individual about HIV testing prior to requesting consent from the individual to perform an HIV antibody test

**Volunteer:** A person who agrees to participate in a clinical trial

**Vulnerable:** Open to emotional danger or physical harm; easily convinced or likely to give in to pressure

## W

**Western blot (WB):** Laboratory test for specific antibodies, which is used to confirm positive results on the HIV *ELISA* or *EIA* tests.

**Wild-type virus:** Viral strains that have not acquired any genetic mutations that create special characteristics, such as *resistance* to particular medicines.

**Window period:** The time period between a person first becoming infected with HIV and the appearance of detectable HIV antibodies. Because antibodies to HIV take some time to form, an HIV antibody test

will not be positive immediately after a person is infected. The time delay typically ranges from 14–21 days, but varies. Nearly everyone infected with HIV will have detectable antibodies by 3 months after becoming infected.

**Withhold:** To hold back or deny treatment

**World Health Organization (WHO):** An agency of the United Nations established in 1948 to further international cooperation in improving health conditions. The World Health Organization was given a broad mandate under its constitution to promote the attainment of “the highest possible level of health” by all people.

# Acronyms

*Commonly Used in HIV Clinical Research*

## A

**ACTG:** AIDS Clinical Trials Group

**ABC:** abacavir

**ABCs of HIV prevention:** abstinence, be faithful, condoms

**ACTU:** AIDS Clinical Trials Unit

**ADAP:** AIDS Drug Assistance Program (state programs in US)

**ADL:** activities of daily living

**ADV:** adefovir dipivoxil

**AE:** adverse event

**AER:** adverse event reporting

**AETC:** AIDS Education and Training Center

**AIDS:** acquired immunodeficiency syndrome

**APV:** amprenavir

**ART:** antiretroviral therapy (or antiretroviral treatment)

**ARV:** antiretroviral

**ATN:** Adolescent Treatment Network

**ATV:** atazanavir

**AZT:** zidovudine, ZDV

## B

**BID:** twice daily

**BMI:** body mass index

**BSA:** body surface area

## C

**CAB:** Community advisory board

**CBC:** complete blood count

**CBO:** community-based organization

**CCWG:** Cross-CAB working group

**CDC:** Centers for Disease Control and Prevention

**CMV:** cytomegalovirus

**CMI:** cell-mediated immunity

**CNS:** central nervous system

**CORE:** Coordinating and Operations Center

**CPCRA:** Community Programs for Clinical Research on AIDS

**CRF:** case report form

**CS:** concept sheet

**CSF:** cerebrospinal fluid

**CSMB:** Clinical Site Management Branch

**CSMG:** Clinical Site Monitoring Group

**CT:** computed tomography

**CTS:** clinical trials specialist

**CTU:** clinical trials unit

## D

**d4T:** stavudine

**d4T-XR:** d4T extended-release capsules

**DACS:** data analysis concept sheet

**DAIDS:** Division of Acquired Immunodeficiency Syndrome

**ddC:** dideoxycytidine (zalcitabine)

**ddl:** 2'2-dideoxyinosine (didanosine,)

**DEXA:** dual-energy x-ray absorptiometry

**DLV:** delavirdine

**DMC:** Data Management Center

**DNA:** deoxyribonucleic acid

**DOT:** directly observed therapy

**DSMB:** Data Safety and Monitoring Board

## E

**EAE:** expedited adverse event

**EBV:** Epstein Barr Virus

**EFV:** efavirenz

**EKG (or ECG):**  
electrocardiogram

**ENF:** enfuvirtide (T-20)

## F

**FDA:** Food and Drug Administration

**FDC:** Fixed-dose combination

**FSTRF:** Frontier Science and Technology Research Foundation

**FTC:** emtricitabine

**F/U:** follow-up

**FXBC:** François-Xavier Bagnoud Center

## G

**GART:** Genotypic Antiretroviral Resistance Test

**GCP:** Good Clinical Practice

**GCRC:** General Clinical Research Center

**GLP:** Good Laboratory Practice

**GI:** Gastrointestinal

**GYN:** gynecology

## H

**HAART:** Highly Active Antiretroviral Therapy

**HBV:** hepatitis B virus

**HCV:** hepatitis C virus

**HIV:** Human immunodeficiency virus

**HIV RNA-PCR:** viral load test (polymerase chain reaction)

**HPTN:** HIV Prevention Trials Network

**HPV:** human papillomavirus

**HSV:** herpes simplex virus

**HVTN:** HIV Vaccine Trials Network

## I

**IBT:** immune-based therapy

**IC:** informed consent

**ICAB:** IMPAACT Community Advisory Board

**ICTU:** International Clinical Trials Unit

**IDU:** injection drug user

**IDV:** indinivir

**IL-2:** interleukin-2

**IM:** intramuscular

**IMPAACT:** International Maternal, Pediatric, and Adolescent AIDS Clinical Trials

**IND:** investigational new drug

**INH:** isoniazid

**INSIGHT:** International Network for Strategic Initiatives in Global HIV Trials

**IRB:** Institutional Review Board

**IRD:** immune restoration disease

**IRIS:** immune reconstitution inflammatory syndrome

**IRS:** immune reconstitution syndrome

## K

**KPS:** Karnofsky Performance Scale

**KS:** Kaposi's sarcoma

## L

**L&D:** labor and delivery

**LDMS:** Laboratory Data Management System

**LFT:** liver function test

**LFU:** lost to follow-up

**LIP:** lymphoid interstitial pneumonitis

**LP:** lumbar puncture

**LPV:** lopinavir

**LPV/r:** lopinavir/ritonavir, LPV/RTV co-formulation

**LSC:** laboratory steering committee

## M

**MAC:** mycobacterium avium complex

**MDR:** multi-drug resistant

**MAI:** mycobacterium avium intracellular

**MDR-TB:** multiple-drug resistant tuberculosis

**MEMS:** Medication Event Monitoring System

**MO:** medical officer

**MPC:** managing partners group

**MRI:** magnetic resonance imaging

**MTCT:** mother-to-child transmission

**MTN:** Microbicide Treatment Network

## N

**NCI:** National Cancer Institute

**NEC:** Network Executive Committee

**NFV:** nelfinavir

**NGO:** Nongovernmental organization

**NIAID:** National Institute of Allergy and Infectious Diseases

**NICHD:** National Institute of Child Health and Human Development

**NIH:** National Institutes of Health

**NIMH:** National Institute of Mental Health

**NNRTIs:** non-nucleoside reverse transcriptase inhibitors

**NRTIs:** nucleoside reverse transcriptase inhibitors

**NtRTIs:** nucleotide reverse transcriptase inhibitors

**NVP:** nevirapine

**NWCS:** new work concept sheet

## O

**OAR:** Office of AIDS Research

**OB:** obstetrics

**OI:** opportunistic infection

**OPS:** operations center

## P

**PACTG:** Pediatric AIDS Clinical Trials Group

**PACTU:** Pediatric AIDS Clinical Trials Unit

**PCP:** Pneumocystis jiroveci pneumonia

**PCR:** polymerase chain reaction

**PEP:** post-exposure prophylaxis

**PEPFAR:** President's Emergency Plan for AIDS Relief

**PERC:** performance evaluation resource committee

**PGL:** persistent generalized lymphadenopathy

**PHACS:** pediatric HIV/AIDS cohort study

**PID:** patient identification number (also pelvic inflammatory disease)

**PI:** principal investigator

**PI:** protease inhibitor

**PK:** pharmacokinetics

**PLWA:** people living with AIDS

**PML:** progressive multifocal leukoencephalopathy

**PMPA:** tenofovir

**PMTCT:** prevention of mother-to-child transmission

**PTCT:** parent-to-child transmission

**PO/po:** by mouth; oral route of administration

**PP:** postpartum (after birth)

**PPD:** purified protein derivative (tuberculin skin test)

**PWA:** person with AIDS

## Q

**QA:** quality assurance

**QC:** quality control

**QD:** once daily

**QID:** four times daily

**QOL:** quality of life

## R

**RAB:** Regulatory Affairs Branch

**RAC:** research agenda committee

**RBC:** red blood cell

**RCAB:** regional community advisory board

**RCC:** Regulatory Compliance Center

**RFA:** request for applications

**RFP:** request for proposals

**RNA:** ribonucleic acid

**RT:** reverse transcriptase

**RTIs:** reverse transcriptase inhibitors

**RTV:** ritonavir

## S

**SAE:** serious adverse event

**SD:** standard deviation

**SDAC:** Statistical and Data Analysis Center

**SGC:** soft-gel capsule

**SID:** study identification number

**SOC:** scientific oversight committee

**SOE:** schedule of events

**SOP:** standard operating procedure

**SQV, SQV-sgc:** saquinavir, saquinavir soft-gel capsule

**SSS:** Social & Scientific Systems

**STD:** sexually transmitted disease

**STI:** structured treatment interruption (also sexually transmitted infection)

## T

**T-20:** fusion inhibitor (enfuvirtide)

**TB:** tuberculosis

**TDF:** tenofovir disoproxil fumarate

**TID:** three times per day

**TZ:** abacavir/lamivudine/zidovudine co-formulation

## U

**UDVL:** undetectable viral load

**ULN:** upper limit of normal

## V

**VCT:** voluntary counselling and testing

**VL:** viral load

**VZV:** varicella zoster virus

## W

**WB:** Western Blot

**WBC:** white blood cell

**WHO:** World Health Organization

**WNL:** within normal limits

## X

**XDR-TB:** extreme multi-drug resistant tuberculosis

## Z

**ZDV:** zidovudine (AZT)

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- For those using this tool, please feel free to send comments or questions to: [info@fxbcenter.org](mailto:info@fxbcenter.org) — Director, IMPAACT International Training Program  
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