

Acronyms and Abbreviations

AE – Adverse event
AIDS – Acquired Immunodeficiency Syndrome
ARV – Antiretroviral drug
CAB – Community Advisory Board
CAG – Community Advisory Group
CBO – Community-Based Organization
CIOMS – Council for International Organizations of Medical Science
EC – Ethics committee
DSMB – Data safety monitoring board
DSMC – Data safety monitoring committee
GCLP – Good Clinical Laboratory Practice
GCP – Good Clinical Practice
GMP – Good Manufacturing Practice
GPP – Good Participatory Practice
HIV – Human Immunodeficiency Virus

IDMC – Independent data monitoring committee
IDU – Injecting drug use
IRB – Institutional review board
MSM – Men who have sex with men
MTN – Microbicide Trials Network
NGO – Non-governmental organization
PEP – Post-exposure prophylaxis
PMTCT – Prevention of mother-to-child transmission
PrEP – Pre-exposure prophylaxis
REC – Research ethics committee
SOP – Standard operating procedure
STI – Sexually transmitted infection
TG – Transgender
UNAIDS – Joint United Nations Programme on HIV/AIDS
WHO – World Health Organization

Glossary

Accrual. The process of recruiting participants into a clinical trial in order to reach target participant numbers.

Acquired immunodeficiency syndrome (AIDS). The most severe manifestation of infection with human immunodeficiency virus (HIV), characterized by deterioration of the immune system and susceptibility to a range of opportunistic infections and cancers. (See human immunodeficiency virus.)

Activist. A person or group who acts on the behalf of a cause in order to bring about change.

Adverse event (AE). An unwanted effect experienced by a participant in a clinical trial. This may or may not be related to the product or procedure being studied.

Advocate. A person or group who advocates on the behalf of individuals, groups, or a specific cause.

Antiretroviral (ARV) drug. A drug or medication that acts against or suppresses a retrovirus such as HIV.

AVAC. An international, non-profit organization that uses education, policy analysis, advocacy and a network of global collaborations to accelerate the ethical development and global delivery of AIDS vaccines, male circumcision, microbicides, PrEP and

other emerging HIV prevention options as part of a comprehensive response to the pandemic.

Biomedical HIV prevention trial. A clinical trial that aims to discover safe and effective products or procedures to prevent HIV transmission.

Blinded trial or masked trial. A clinical trial designed to prevent the participants, research teams, or both, from knowing which participants are in the experimental arm or group and which are in the control arm or group of a trial, in order to reduce bias.

Clinical trial. A research study that uses human volunteers to answer specific questions about the safety, efficacy or effectiveness, and medical effects of a specific procedure, medication, product, or treatment. A clinical trial process may include Phases I, II, IIb, III, and IV (post-marketing evaluation).

Community advisory boards (CABs) or community advisory groups (CAGs). Boards or groups composed of individuals or stakeholder representatives that act as an independent advisory voice and facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders

about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise in specific trials.

Community-based organization (CBO). A public or private not-for-profit group (including a church or religious entity) that is representative of a community or a significant segment of a community, and is engaged in meeting human, educational, environmental, or public health or safety community needs, often organized as close as possible to the individuals it serves.

Community groups. Groups of individuals who come together to act on behalf of common interests, goals, and values but whose organization does not require formal designation or registration.

Community stakeholders (per the GPP guidelines). Individuals and groups who are ultimately representing the interests of people who would be recruited to or participate in a clinical trial, and others locally affected by a trial. Examples of “community stakeholders” are the population to be recruited, trial participants, people living in the area where the research is conducted, people living with HIV in the area, local HIV-positive groups or networks, people in the area affected by the HIV epidemic, local non-governmental organizations, community groups, and community-based organizations. (See stakeholders.)

Confidentiality. The principle that protects the rights of trial participants regarding prevention of unauthorized disclosure of personal information to third parties during data collection, storage, transfer, and use.

Condom. A sheath or pouch that is worn either over the penis (male condom) or inside the vagina (female condom) during sexual intercourse, for the purpose of protecting against sexually transmitted infections (including HIV) or preventing pregnancy. (See female condom or male condom.)

Control arm or group. The group of participants in a clinical trial who receive the placebo or control product or procedure. (See placebo.)

Data and safety monitoring board (DSMB) or independent data monitoring committee (IDMC). An independent committee established by a trial sponsor to assess, at intervals, the progress of a clinical trial, safety data, and critical efficacy or effectiveness endpoints. A data and safety monitoring board may recommend to the sponsor that a trial be stopped or modified if there are safety concerns, if trial objectives have been achieved, or if assessment of trial progress reveals that continuing the trial would be futile since it will no longer be possible to answer the research question that the trial is addressing.

Design and conduct of biomedical HIV prevention trials (per the GPP guidelines). Activities required for the development, planning, implementation, and conclusion of a trial, including dissemination of trial results

Ethics committee. See research ethics committee.

Experimental arm or group. The group of participants in a clinical trial who receive the procedure, product, or drug being studied.

Female condom. A pouch that when inserted in the vagina before vaginal intercourse, provides protection against most sexually transmitted infections, including HIV, and pregnancy. During anal sex, the female condom, when placed on the penis after removing the inner ring, provides protection against most sexually transmitted infections, including HIV. Currently made of polyurethane (female condom 1) or a synthetic latex (female condom 2), it is stronger than the natural latex used in male condoms, odourless, non-allergenic, and usable with oil-based and water-based lubricants. For vaginal intercourse, it can be inserted vaginally prior to intercourse, is not dependent on male erection, and does not require immediate withdrawal after ejaculation. (See also male condom.)

Formative research activities. Activities that enable research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, channels of communication and decision-making, and local history of research, as well as the needs and priorities of people locally affected by or able to influence a clinical trial. Formative research activities usually constitute the initial phase of stakeholder outreach and engagement.

Futility. The inability of a clinical trial to achieve one or more of its objectives. This determination may be suggested, for example, during an interim analysis of a trial by a data safety monitoring board.

Good Clinical Laboratory Practice (GCLP).

Guidelines that set a standard for compliance by laboratories involved in the analysis of samples from clinical trials. These guidelines provide guidance to ensure that trial laboratory data are reliable, repeatable, auditable, and easily reconstructed in a research setting.

Good Clinical Practice (GCP). Internationally recognized guidelines for designing, conducting, recording, and reporting clinical trials in which humans participate. GCP provides guidance to ensure that trial data are credible

and to protect the rights, safety, and well-being of trial participants. The guidelines were issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

Good Manufacturing Practice (GMP). Quality assurance practices that ensure that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. Good manufacturing practices are aimed primarily at diminishing the risks inherent in any pharmaceutical or medical device production.

Good Participatory Practice (GPP). Guidelines that provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with stakeholders in the design and conduct of biomedical HIV prevention trials.

HIV vaccine (or AIDS vaccine). A vaccine designed to prevent HIV infection. (See vaccine.)

Human immunodeficiency virus (HIV). The virus that weakens the immune system, ultimately leading to acquired immunodeficiency syndrome (AIDS).

Implementer. See trial implementer.

Informed consent. A process by which a competent individual voluntarily confirms his or her willingness to

participate in a particular clinical trial after having been informed of all aspects of the trial that are relevant to the individual's decision to participate. Informed consent is an ongoing process throughout the course of a clinical trial.

Institutional review board (IRB). See ethics committee.

Male condom. A sheath designed to be worn over the penis during vaginal, anal, or oral intercourse as a means of preventing sexually transmitted infections, including HIV, or preventing pregnancy in the case of vaginal intercourse. (See also female condom.)

Medical male circumcision. The surgical removal of the entire foreskin of the penis. Three clinical trials conducted in sub-Saharan Africa have shown that medically performed male circumcision is safe and can reduce men's risk of HIV infection during vaginal sex by about 60%. Prevalence of male circumcision varies by geography, religion, and cultural practices.

Men who have sex with men (MSM). Men who have sexual contact with other men, regardless of whether or not they also have sex with women or have a personal or social gay or bisexual identity. This concept also includes men who self-identify as heterosexual but have sex with other men.

Microbicides. A range of products that could be used vaginally or rectally (such as a gel, cream, ring, film, suppository or sponge) that are being tested to determine if they reduce or prevent the transmission of HIV and other disease-causing organisms during vaginal and anal intercourse.

Network or research network. A cooperative of research institutions or centres conducting clinical trials under a common research agenda.

Non-governmental organization (NGO). A not-for-profit, registered entity or group that is organized on local, national, or international levels but is not an agency of local or national governments.

Placebo. An inactive substance that is designed to appear like an experimental product being studied in all aspects except for the absence of the active ingredient under study. In clinical trials, the safety and

effectiveness of an experimental product are assessed by comparing data from the experimental product trial arm to those from the placebo arm.

Post-exposure prophylaxis (PEP). Antiretroviral medicines prescribed and taken after exposure or possible exposure to HIV, to reduce the risk of acquiring HIV. The exposure may be occupational, as in a needle stick injury, or non-occupational, as in the case of rape. **Pre-exposure prophylaxis (PrEP).** Antiretroviral drugs used by a person who does not have HIV infection to be taken before possible exposure to HIV in order to reduce the risk of acquiring HIV infection.

Product or trial arm assignment. The specific study product or procedure, such as the experimental or 'active' arm or the placebo arm, to which a participant is assigned for the designated follow-up period. (See placebo and experimental arm.)

Protocol. A document that details the rationale, goals, design, methodology, statistical considerations, and organization of a study or clinical trial. A protocol describes a scientific study designed to answer specific research questions and describes how the health of the trial participants will be safeguarded.

Randomization. A method based on chance alone by which trial participants are assigned to a trial arm or group. Randomization ensures that the only intended difference between trial arms or groups is which product or procedure a trial participant is exposed to during the trial.

Randomized trial. A clinical trial in which participants are assigned by chance to one of the trial arms or groups. (See randomization.)

Regulatory authorities. Government agencies charged with carrying out the intent of legislation that constrains the actions of private individuals, businesses, organizations, institutions, or government bodies. In most countries, one or more regulatory agency may be responsible for ensuring the safety and effectiveness of health products and the correct conduct of clinical trials.

Research ethics committee (REC) or institutional review board (IRB). An independent body made up of medical, scientific, and non-scientific members whose

responsibility is to protect the rights, safety, and wellbeing of human participants involved in a clinical trial. Research ethics committees review and approve the initial protocol, review materials to be used in recruiting and consenting trial participants, and provide continuing review of a trial protocol and any amendments. The term "institutional review board" is common in the United States of America, whereas other countries commonly use the term "research ethics committee" or "independent ethics committee".

Research network. See network.

Research team. A group of investigators and staff involved in implementing biomedical HIV prevention trials. Research teams can include investigators and staff at a specific trial site as well as investigators and staff working at coordinating centres, institutions, or agencies.

Scientific process. A recognized systematic way to form and test hypotheses by designing controlled experiments to collect data, analyze results, and draw conclusions in order to acquire new knowledge or to correct, refine, and integrate previous knowledge.

Seroconversion. The process by which a newly infected person develops antibodies that can be detected by an HIV antibody test. Development of antibodies may occur anywhere from weeks or months following HIV infection.

Sexually transmitted infections (STIs). Infections caused by microorganisms that are transmitted from one person to another during sexual or intimate contact.

Stakeholders or trial stakeholders. Individuals, groups, organizations, governments, or other entities that are affected by the outcome of a biomedical HIV prevention trial or that can influence proposed research through their input and actions. (See community stakeholders.)

Stakeholder engagement. Processes through which trial funders, sponsors, and implementers build transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organization, with the ultimate goal of shaping research collectively.

Standard operating procedure (SOP). A document that gives step-by-step instructions for how to conduct a procedure, in order to ensure that each staff member can perform the procedure in the same way.

Stigma. AIDS-related stigma refers to a pattern of prejudice, discounting, discrediting, and discrimination directed at people perceived to have HIV or AIDS, their significant others and close associates or their social groups.

Tenofovir. An antiretroviral drug that decreases the amount of HIV in the blood by inhibiting (or stopping) replication of the virus. Tenofovir is sometimes used alone or in combination with other antiviral medications. Marketed by Gilead under the brand name Viread for HIV treatment; it is also being tested for prophylactic use to prevent infection among uninfected individuals, an intervention generically known as PrEP.

Therapeutic HIV vaccine. A compound designed to stimulate the immune response to HIV in a person already infected with the virus, in order to control the infection. Also referred to as an immunotherapeutic vaccine. (See vaccine and HIV vaccine.)

Transgender (TG) individual. A person who identifies with or expresses a gender other than their sex assigned at birth, or biological gender. “Transgender woman” refers to a person who identifies as a female but was assigned a “male” sex at birth.

Trial arm or group. A group within a clinical trial formed of participants who have been assigned a particular product or procedure during a trial. (See control arm or group, experimental arm or group.)

Trial funder. An individual or entity responsible for financing the cost of a trial.

Trial implementer. Investigators, research staff, and all others specifically responsible for executing biomedical HIV prevention trials. Implementers may be employed by governments, government-sponsored networks, non-governmental organizations, academic institutions, the pharmaceutical industry or other companies, foundations, or public–private partnerships.

Trial life-cycle. The entire process of a trial, starting from developing the initial concept and writing the protocol and continuing through to the implementation and conduct of the trial to completion, exiting of participants, and dissemination and reporting of results.

Trial participant. A competent individual who voluntarily provides informed consent to participate in a clinical trial. Trial participants are assigned to a particular trial arm or group, in which they receive a particular product or procedure.

Trial sponsor. An entity that is responsible for a trial but that does not actually conduct it. The sponsor may be a pharmaceutical company, governmental agency, academic institution, or private or other organization.

UNAIDS (Joint United Nations Programme on HIV/AIDS). UNAIDS brings together the resources of the UNAIDS Secretariat and 10 UN system organizations to lead and inspire the world in achieving universal access to HIV prevention, treatment, care, and support.

Unblinding or unmasking. The process of revealing trial participants’ product or procedure assignments. Unblinding involves informing participants about which product they were assigned to during the trial.

Vaccine. A compound that stimulates the body’s immune response in order to prevent or control an infection. A vaccine is typically made up of parts of a bacterium or virus that cannot itself cause an infection. (See HIV vaccine.)