Research Ethics Glossary

Term	Definition
Action Research	see also Research design.
Action Research	A style of research in which the researchers work with the people and for the people, rather than undertake research on them. The focus of action research is on generating solutions to problems identified by the people who are going to use the results of research
Adenocarcinoma	A malignant tumor originating in glandular tissue.
Adjuvant therapy	Treatment that is given in addition to the primary treatment. For example, adjuvant therapy for cancer usually refers to surgery followed by chemo- or radiotherapy to help decrease the risk of the cancer coming back.
Adverse Drug Reaction (ADR):	In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out. Regarding marketed medicinal products, ADR is a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function. (See also Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR)
Adverse event (AE)	In the context of a clinical trial, any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.
Allopathic	Refers to conventional evidence-based medical practice in contrast to homeopathy, ayurveda and alternative therapies and interventions.

Analytic study	An epidemiological study to test the hypothesis that a factor is the cause of a health effect, for instance that the factor causes a disease or that it prevents a disease. The most common types of analytic studies are case-control, cohort and cross-sectional studies. Analytic studies are contrasted with descriptive studies, which do not test hypotheses. In addition to these types of studies, all of which are observational, analytic studies also encompass interventional studies.
Ancillary Care	"Ancillary Care is that which is not required to make a study scientifically valid, to ensure a trials safety, or to redress research injuries. Thus, stabilising patients to enrol them in a research protocol, monitoring drug interactions, or treating adverse reations to experimental drugs are not ancillary care. By contrast, following up on diagnosis found by protocol tests or treating ailents that are unrelated to the study's aims would be ancillary care." (from Belsky L., and Richardson HS Medical researchers' ancillary clinical care responsibilities BMJ. 2004 Jun 19;328(7454):1494-6.)
Anemia (Anaemia)	A condition in which the haemoglobin concentration in the blood is below a defined level, resulting in a reduced oxygen-carrying capacity of red blood cells. About half of all cases of anaemia can be attributed to iron deficiency; other common causes include infections, such as malaria and schistosomiasis, and genetic factors. The major health consequences include poor pregnancy outcome, impaired physical and cognitive development, increased risk of morbidity in children and reduced work productivity in adults. Pregnant women and children are particularly vulnerable. Anaemia contributes to 20% of all maternal deaths.
Anonymization	To make anonymous. Research records or biological samples from which all direct or indirect identifiers have been removed such that no link is possible between the records or samples and the identity of the person who was the source of the record or sample (CIOMS - http://www.cioms.ch/)
Anonymous	A record, biological sample or item of information that in no circumstance can be linked to an identified person. (CIOMS - http://www.cioms.ch/)
Antipsychotic drug	A drug used to treat psychosis, a group of mental disorders characterized by confusion, delusions and hallucinations.
Antiretroviral (ARV)	A group of medicines used in the treatment of HIV/AIDS. Antiretroviral treatment (ART) suppresses or stops the HIV retrovirus that causes AIDS.

Arm	In a clinical trial, an ‘arm’ is an assigned group, for example a trial may include a placebo arm and an investigational intervention arm. Some types of trial design include more than two arms. Participants are usually randomly assigned to these groups. (http://globalhealthreviewers.tghn.org/resources/glossary/)
Arrhythmia	An irregularity in the force or rhythm of the heartbeat. It some cases it can cause cardiac arrest and sudden death.
Assent	A variation on consent wherein a person who does not possess full competence to give informed consent gives affirmative agreement to participate in research. For instance, a child or person with dementia should give assent before being enrolled in research. However, it is important to note that assent does not eliminate the need for obtaining the permission of a parent or other legally authorized decision-maker.
Audit	A systematic and independent examination of trial related activities and documents to determine whether the evaluated trial related activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s) (CIOMS - http://www.cioms.ch/).
Autonomy	Respecting a participant’s autonomy involves respecting their capacity to make decisions about research participation, either on an individual basis, or following discussion with others, such as family members. (http://globalhealthreviewers.tghn.org/resources/glossary/)

Ayurveda	An ancient system of health care that is native to the Indian subcontinent. The word "Ayurveda" is a derived from the sanskrit words *āyus* meaning "life," "life principle," or "long life" and the word *veda* , which refers to a system of "knowledge." Ayurveda means 'the knowledge needed for long life'. According to the Ayurveda principles, health or sickness depends on the presence or absence of a balanced state of the total body matrix including the balance between its different constituents. Both the intrinsic and extrinsic factors can cause disturbance in the natural equilibrium giving rise to disease. This loss of equilibrium can happen by dietary indiscrimination, undesirable habits and non-observance of rules of healthy living. The treatment consists of restoring the balance of disturbed body-mind matrix through regulating diet, correcting life-routine and behaviour, administration of drugs and resorting to preventive therapy. From Ministry of Health and Family Welfare, India. See indinmedicine.nic.in/ayurveda.asp
Baseline data	Data or measurements collected at the outset of implementation of a surveillance system or of strengthening activities, or a set of indicators that have been identified to monitor and evaluate the performance of a surveillance and response system. For example, the baseline mortality rate (or non-crisis mortality rate) is mortality rate before the crisis.
Before-and-after study	A control study in which results from research participants in the experimental group are compared with the outcomes from patients treated before the new intervention was available. These are called 'historic controls'
Beneficence	Refers to the ethical obligation to maximize benefit and to minimize harm. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be sound, and that the investigators be competent both to conduct the research and to safeguard the welfare of the research subjects. Beneficence further proscribes the deliberate infliction of harm on persons; this aspect of beneficence is sometimes expressed as a separate principle, ***nonmaleficence*** (do no harm).

Benefit	A favourable consequence arising from a study, for example the demonstration that a vaccine is effective in a randomized controlled trial or the identification of a workplace hazard in an observational study. Benefits are often contrasted to 'risks' (as in a 'risk/benefit ratio') but the term 'risk' is ambiguous because it connotes both an adverse consequence and the probability of its occurrence (i.e., risk in the formal epidemiological meaning). To avoid this ambiguity, the term 'risk' is better replaced by 'harm' when the consequence is certain or has already occurred, or 'potential harm' when it remains a possibility. In the context of planned research, the balance to be struck is thus between potential benefits (to society and possibly to the subjects) and potential harms (principally to research participants but can also include their communities more broadly), paying attention both to the type and magnitude of these benefits and harms and the probability that they will occur. Potential benefits and harms to participants may not be restricted to them, but may extend to their family members or, more generally, to a group to which they belong. For instance, findings of a higher than average prevalence of certain genetic traits or diseases among study subjects may offer a means of early assessment and prevention (a benefit for the group of which they are a part) but may also stigmatize the family or the group in the eyes of others (a harm for the group).
Beta-carotene	An antioxidant found in many vegetables which is partly converted to vitamin A by the liver. Scientists believe that beta-carotene as found in fresh fruit and vegetables has properties that can contribute to reducing cancer and heart disease.
Bias/Non-sampling error	Systematic error during data collection which results in a distortion of the findings (in mortality studies, an over- or under-estimation of mortality).
Bioethics	A field of ethical inquiry that examines ethical issues and dilemmas arising from health, health care and research involving human beings.
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.
Blinding/Masking	A procedure in which one or more parties to the trial are kept unaware of the treatment assignments(s). Single-blinding usually refers to the subject(s) being unaware and double-blinding usually refers to the trial participant(s), investigator(s), monitor, and, in some cases, data analyst(s) being unaware of the treatment assignment(s). See blinded trial or masked trial.

CABs/CAMs	Community Advisory Boards/Mechanisms. see Community Advisory Boards
Carcinoma in situ (CIS)	An early form of carcinoma (malignant cancer). It is an accumulation of neoplastic (abnormal) cells that have not spread to surrounding tissues. If left untreated, *carcinoma in situ* can transform into cancer
Case-control study	See Research Design.
Case-control study	An observational study design that starts with the identification of individuals with the outcome of interest, such as a disease (cases), and individuals. without the outcome of interest (controls). The frequencies of exposures to potential risk or protective factors for the outcome of intrest are compared in cases and controls
Chlamydia	A sexually transmitted infection caused by the small bacterium *Chlamydia trachomatis* . In men it can cause inflammation of the urethra, conjunctiva of the jonts, and in women it can cause acute inflammation of the reproductive tract leading to complications such as infertility, potentially fatal ectopic pregnancy, or chronic pain.
Chloroquine	A drug long used in the treatment or prevention of malaria. Over time, the species of protozan parasite *Plasmodium falcinarum (P. falcinarum)* that causes the worst malaria in humans, has developed widespread resistance against chloroquine.
Cholera	Cholera is an acute intestinal infection caused by ingestion of food or water contaminated with the bacterium *Vibrio cholerae* . It has a short incubation period, from less than one day to five days, and produces an enterotoxin, a harmful substance that causes a copious, painless, watery diarrhoea that can quickly lead to severe dehydration and death if treatment is not promptly given. Vomiting also occurs in most patients. Cholera is an easily treatable disease. The prompt administration of oral rehydration salts to replace lost fluids nearly always results in cure. In especially severe cases, intravenous administration of fluids may be required to save the patient's life. Left untreated cholera can kill quickly following the onset of symptoms.
CIOMS	Council for International Organizations of Medical Sciences

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects	The Council for International Organizations of Medical Sciences (CIOMS) is an international nongovernmental organization in official relations with the World Health Organization (WHO). It was founded under the auspices of WHO and the United Nations Educational, Scientific and Cultural and Organization (UNESCO) in 1949 with among its mandates that of maintaining collaborative relations with the United Nations and its specialized agencies, particularly with UNESCO and WHO. The CIOMS (Council for International Organizations of Medical Science) Guidelines, are designed to be of use to countries in defining national policies on the ethics of biomedical research involving human subjects, applying ethical standards in local circumstances, and establishing or improving ethical review mechanisms. A particular aim is to reflect the conditions and the needs of low-resource countries, and the implications for multinational or transnational research in which they may be partners. Like the *Declaration of Helsinki* (see below), the CIOMS Guidelines provide important guidance on the ethical conduct of health research.
CIOMS International Ethical Guidelines for Epidemiological Studies	CIOMS (Council for International Organizations of Medical Science) Guidelines for Epidemiological Studies provide ethical guidance for epidemiologists, as well as those who sponsor, review, or participate in epidemiological studies, on identifying and responding to the ethical issues that are raised by the process of producing this knowledge.
Clinical trial	Any research study that prospectively assigns individual research participants, or groups of research participants, to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, and preventive care.
Clinical trial registry	A clinical trials register is the formal record of an internationally agreed minimum amount of information about a clinical trial. This record is usually stored in and managed using a database. A clinical trials registry is the entity that houses the register, and is responsible for ensuring the completeness and accuracy of the information it contains, and that the registered information is used to inform health care decision making. A clinical trials registry is more than its database .

Cluster sampling	A sampling design commonly used in retrospective mortality surveys when comprehensive lists of individual households cannot be obtained. Clusters are groups of households of which the first is chosen at random, and the remainder by a rule of proximity (e.g. second closest). In a cluster mortality survey, 30 or more clusters are usually sampled from the target study population, and each cluster usually contains at least 30 households.
Coercion	A threat designed to force someone to take part in research, whether or not they want to. (http://globalhealthreviewers.tghn.org/resources/glossary/)
Cohort	A group of individuals with a common characteristic (epidemiological and statistical term). For example, the group may all have been born in a certain year, share a disease and another factor (e.g. age and disease onset time), lifestyle characteristics such as being a smoker, and so on. Cohort studies often therefore involve observing a group with a common characteristic over a period of time, so that the epidemiological effects of the characteristic can be observed. (http://globalhealthreviewers.tghn.org/resources/glossary/)
Cohort study	A longitudinal prospective observational study in which one group of people, a 'cohort', are compared over time to another group with similar characteristics but for whom there is an important difference. For example, a cohort who lives close to a polluting factory and breathes in that air may be compared to a cohort living much further from the factory and the study may show a significant difference in lung capacity or asthama rates.
Community	May be defined as groups of people who can be identified by one or more of the following: place of residence (location or neighbourhood), activity (for example, employment), or who identify around an identity, activity or function.
Community advisory boards (CABS)	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. From UNAIDS/AVAC Good Participatory Practices 2011.

Compensation	Money, vouchers or other forms of recompense given to participants in research to compensate for their time and participation.
Competent person	A person capable of understanding the meaning of the information he/she is presented with and of taking decisions based on it. Certain persons, such as children up to a specified age are typically deemed by the law to be legally incompetent, while others, including people whose mental capacity or thought processes are impaired by mental or physical illness, can be found by a court or other body to be incompetent to make some or all decisions.
Compliance	Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements, and the applicable regulatory requirements.
Confidence interval	A range that expresses the level of approximation, or imprecision, around the point estimate. Also known as a margin of error. 95% confidence intervals are usually presented: we are thus 95% confident that the true population estimate lies within the range of the confidence interval (ODI/HPN paper 52, 2005)
Confidentiality	The obligation to keep information secret unless its disclosure has been appropriately authorized by the person concerned or, in extraordinary circumstances, by the appropriate authorities.
Conflict of interest	In the research context, scientists have a conflict of interest if they stand to achieve personal gain (money or the equivalent) by failing to discharge professional obligations either to protect the welfare of participants or to uphold the integrity of the scientific process.
Conflict of mission	In biomedical and health research, the division between the interests of research participants and those of the researchers is sometimes called a 'conflict of mission', and may be evident in clinical trials in which a physician assumes the role of investigator towards his/her patients (who are then simultaneously patients and research participants. Such 'therapeutic research' serves as a reminder that when two activities (therapy and research) are combined, it is easy to forget how divergent their activities really are.
Contract research organization (CRO)	A person or an organization (commercial, academic, or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions.
Contralateral	Relating to or denoting the side of the body on which a particular structure or condition occurs

Control group	The control group consists of research participants who are not given the intervention which is being tested in the research and compared with a group who are given the intervention. In clinical trials, the intervention would normally be a novel treatment, such as a medicine or vaccine but interventions may also be social and behavioural in nature, for example, safe sex campaigns.
Convenience survey	Survey that is not based on a randomly selected, representative sample, but rather on data from households/individuals that can easily be reached or observed (e.g. people standing in a food-distribution queue)
Cost effectiveness analysis (in surveillance)	This form of analysis seeks to determine the costs and effectiveness of surveillance and response strategies and activities. It can be used to compare similar or alternative strategies and activities to determine the relative degree to which they will obtain the desired objectives or outcomes. The preferred strategy or action is one that has the least cost to produce a given level of effectiveness, or provides the greatest effectiveness for a given level of cost.
Cross-sectional study	An observational study in which the presence of a disease (or other health condition) and the presence of factor(s) of interest are simultaneously ascertained at a point in time in order to examine their relationship. The ascertainment is often carried out in random representative samples of a population. For example, a factor such as blood pressure and a health condition as defined by an electrocardiogram may be measured in subjects selected at random within each age- and sex-specific stratum of a population.
Data Safety Monitoring Board (DSMB)or committee	Constituted and functioning under the authority of the sponsor, a DSMB is an independent advisory body responsible for assessing data during the course of a study in a manner that contributes to the scientific and ethical integrity of the study. The DSMB's recommendations provide the sponsor with an overall scientific, safety, and ethical appreciation of the study, and should assist the sponsor in maintaining the rigour of the study design, with appropriate attention paid to the protection of human subjects.
Deception research	see Research design
Deception research	Research in which the participants are not informed about the nature of the research or even that they are part of a research project.

Descriptive study	An observational study portraying the occurrence of a disease or of other health-related events in relation to geographical areas, calendar periods and demographic characteristics of populations, such as age, sex, educational level, occupation, socioeconomic conditions, etc. These studies can be carried out as “ad hoc” research investigations or as institutional and regular activities of disease surveillance within public health practice. In both contexts they contribute to generating hypotheses on the factors potentially determining the observed disease patterns. These hypotheses can then be tested in analytic studies whose results may in turn be used to verify how much the factors account for the disease patterns. Descriptive studies usually make use of individual records as available in existing databases or registries (of deaths, of notifiable communicable diseases, of cancer, etc.) and do not require identification of the persons to whom the records belong.
Design effect	Phenomenon caused by cluster sampling, and which increases the sampling error or imprecision. Households/individuals within a cluster resemble each other because of their proximity, thus resulting in an overall loss in sampling variability
Distributive justice	See justice
DoH	Declaration of Helsinki (see The Declaration of Helsinki)
Double-blind study	*see Research design or Blinding/Masking*
Double-blind study	A research study design in which the research participant and the researcher don't know whether the participant is receiving the intervention being tested or a comparison intervention which could be either a real medical intervention or a placebo. A randomised control trial may be blinded if participants in the trial are likely to change their behaviour in a systematic way that may influence the outcome of the study when they are aware of which intervention they receive. The purpose is to avoid unconscious subjective bias affecting the study outcome. At the end of the trial, the intervention is unmasked. If problems arise in the course of the trial, specifically any danger to the health or safety of the participants, the trial will also be unmasked to ensure participants' safety.
DSMB	Data Safety Monitoring Boards
Dysentery	Any of various disorders marked by inflammation of the intestines, especially of the colon, and attended by abdominal pain ,and frequent stools containing blood and mucus. Causes include chemical irritants, bacteria, protozoa and parasitic worms.

Dysplasia	Abnormal development or growth of tissues, organs, or cells. It is the earliest form of pre-cancerous lesion. Dysplasia can be diagnosed as either high or low grade, with high grade dysplasia indicative of a more advanced progression towards malignant transformation.
Effectiveness	The degree to which an intervention has a definite or desired effect in a specific context.
Efficacy	The extent to which an intervention can have a desired effect under ideal or controlled circumstances, such as in a clinical trial. Efficacy can be compared to 'effectiveness', which refers to the desired effect in real life circumstances.
Electroencephalography (EEG)	A painless non-invasive and safe procedure whereby the electrical activity of the brain is registered, amplified and recorded by placing a number of electrodes in a specific manner on the head.
Endpoint	The point in a trial or other type of research at which the predetermined target or goal has been reached.
Epidemic	The occurrence in a community or region of cases of an illness, specific health-related behaviour, or other health-related events clearly in excess of normal expectancy. The community or region and the period in which the cases occur are specified precisely. The number of cases indicating the presence of an epidemic varies according to the agent, size, and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence.
Epidemiology	The study of the distribution and determinants of health-related states or events in specified population, and the application of this study to control of health problems.
Equipoise	A state of genuine uncertainty on the part of the expert medical community regarding the therapeutic merits of each arm in a trial

Equity	The fair distribution of benefits and burdens. Equity is the absence of avoidable or remediable differences among populations or groups defined socially, economically, demographically, or geographically; thus, health inequities involve more than inequality—-whether in health determinants or outcomes, or in access to the resources needed to improve and maintain health—-but also a failure to avoid or overcome such inequality that infringes human rights norms or is otherwise unfair. In some circumstances, therefore, an equal distribution of benefits and burdens will be considered fair, while in others it may be equitable to give preference to those who are in most need or are the most vulnerable. A characteristic common to groups that experience health inequities (e.g., poor or marginalized persons, racial and ethnic minorities, and women) is lack of power in political, social, and/or economic terms. Thus, to be effective and sustainable, interventions that aim to redress inequities must typically go beyond remedying a particular health inequality and also help empower the group in question through systemic changes, such as law reform, changes in economic or social relationships, or the like.
Equivalency trial	Compares an investigational intervention with an established effective intervention. Its purpose is to determine whether the investigational intervention is, in effectiveness and safety, equivalent to, or almost equivalent to, the established effective intervention.
ERC	Ethics Review Committee
Ethical guidelines	Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice
Ethical Review	Based on certain set of criteria, a proposal is submitted for review. See also: Exempt from review, Expedited review and Full Committee review
Ethnicity	The collective identity shared by a group of people of common descent or origin.
Exclusion criteria (see also 'Inclusion criteria)	The criteria used to determine whether a person may or may not be allowed to participate in a clinical trial. The most important criteria used to determine appropriateness for clinical trial participation include age, sex, the type and stage of a disease, treatment history, and other medical conditions. See *Inclusion criteria* .
Exempt from Review	Proposals may be exempt from ethical review if they meet certain criteria, for example if there is no possibility of harm arising as a result of the conduct of the research project or if the information being evaluated is already available in the public domain.

Expedited Review of Proposals	Depending on the criteria of the specific committees reviewing research, a proposal may be circulated for expedited review when the research procedures present no more than minimal harm to the research participants or communities.
Externally-sponsored research	Refers to research undertaken in a host country but sponsored, financed, and sometimes wholly or partly carried out by an external international or national organization or pharmaceutical company with the collaboration or agreement of the appropriate authorities, institutions and personnel of the host country.
Fair subject selection	The ethical principle of justice, specifically of distributive justice, requires that the risks, burdens and benefits of research, and participation in research be equitable as far as possible.
Focus Group Discussion (FGD)	A group discussion of approximately 6 - 12 persons guided by a facilitator, during which group members talk freely and spontaneously about a certain topic. The purpose of using this qualitative research methodology is to obtain in-depth information on the concepts, perceptions and ideas of a group.
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 (From: UNAIDS (2011) Good participatory practice: Guidelines for biomedical HIV prevention trials, UNAIDS)
Full Committee Review of Proposals	All research proposals that present more than minimal risk to human subjects are reviewed by two primary reviewers who present the proposal to the Committee followed by a general discussion and a consensus decision. The WHO technical officers responsible for the proposal under review are invited to respond to queries raised and to provide clarifications and/or justifications .
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." UNAIDS (2011) Good participatory practice: Guidelines for biomedical HIV prevention trials, UNAIDS)
GCP	see Good Clinical Practice

Gender	Gender refers to the *socially constructed* roles, behaviours, activities, and attributes that a given society *considers appropriate* for men and women (as opposed to 'sex', which refers to those which are biologically determined). To put it another way: “Male” and “female” are sex categories, while “masculine” and “feminine” are gender categories. Aspects of sex will not vary substantially between different human societies, while aspects of gender may vary greatly.
Gender discrimination	Refers to any distinction, exclusion or restriction made on the basis of socially constructed gender roles and norms which prevents a person from enjoying full human rights.
Gentamycin	An antibiotic used to treat many different bacterial infections. Gentamycin is not effective when given orally because it is deactivated when absorbed by the small intestine and filtered into the liver. It can only be given intravenously, intramuscularly or topically.
Gonorrhoea	A sexually transmitted infection caused by the bacterium *neisseria gonorrhoeae. While gonorrhoea can often be asymptomatic in both men and women,* it is usually characterized by genital discharge, painful urination, and inflammation and infection of the urethra and, in women, inflammation of the reproductive tract.
Good Clinical Practice (GCP)	Good Clinical Practice (GCP) is an ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects, that has its origin in the International Conference on Harmonization (ICH). Compliance with this standard provides public assurance that the rights, safety and well-being of trial subjects are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinical trial data are credible. Although it concerns good *research* practices, the term *clinical* is used to distinguish these standards from those that apply to good *laboratory* and good *manufacturing* practices for pharmaceuticals.
Guidelines (Ethical guidelines)	Guidance documents which assist with decisions relating to the responsibility to adhere to established and relevant standards of ethical principles and practice.
Health determinants	The personal, social, cultural, economic and environmental factors that influence the health status of individuals or populations (EURO European Centre for Health Policy, ECHP, Brussels, 1999).

Health impact assessment	A combination of procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population (EURO European Centre for Health Policy, ECHP, Brussels, 1999). From WHO site http://www.who.int/hac/about/definitions/en/index.html
Hepatitis B (HBV)	Hepatitis is an inflammation of the liver, most commonly caused by a viral infection. There are five main hepatitis viruses, referred to as types A, B, C, D and E. Hepatitis A and E are typically caused by ingestion of contaminated food or water. Hepatitis B, C and D usually occur as a result of parenteral contact with infected body fluids (e.g. from blood transfusions or invasive medical procedures using contaminated equipment). Hepatitis B is also transmitted by sexual contact. The symptoms of hepatitis include jaundice (yellowing of the skin and eyes), dark urine, extreme fatigue, nausea, vomiting and abdominal pain.
Histology	The word "histology" came from the Greek "histo-" meaning tissue + "logos", treatise, so histology is the scientific study of tissue.
Human rights	Refers to the "basic rights and freedoms to which all humans are entitled." Examples of rights and freedoms which are often thought of as human rights include civil and political rights, such as the right to life, and liberty, freedom of expression and equality before the law; and social, cultural and economic rights, including the right to participate in culture, the right to food, the right to work and the right to education. On December 10, 1948 the General Assembly of the United Nations adopted and proclaimed the Universal Declaration of Human Rights as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind, shall strive by teaching and education to promote respect for these rights and freedoms and by progressive measures, national and international, to secure their universal and effective recognition and observance, both among the peoples of Member States themselves and among the peoples of territories under their jurisdiction. Some of the most important characteristics of human rights are that they are: universal, guaranteed by international standards; legally protected; focus on the dignity of the human being; and cannot be waived or taken away;
IC	Informed consent
ICF	Informed consent form

ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
Identifiable material	This includes nominal record or samples (records and samples that carry the person's name or unique identifier such as a social security number), and secondly, linked, coded record or biological samples (a record or sample that does not carry a name but is coded and thus, by possessing or by "breaking" the coding system, could be linked to the person to whom the record refers or from whom the sample was obtained). The code may be kept by the researcher or the sponsor or a third party. See CIOMS Epidemiological guidelines at http://www.cioms.ch/)
Identifiable material (see also Non-identifiable material)	Includes nominal records or samples and linked, coded records or biological samples. Nominal records or samples carry a person's name or unique identifier, such as a social security number. Linked, coded records or biological samples do not carry a name but are coded and thus, by possessing or breaking the coding system, could be linked to the person to whom the record refers or from whom the sample was obtained. The code might be kept by the researcher or the sponsor or a third party. Identifiable materials are of three types: i. Nominal record or sample: Records and samples that carry the person's name or unique identifier, such as a social security number. ii. Linked, coded record or biological sample: A record or sample that does not carry a name but is coded and thus, by possessing or by "breaking" the coding system, could be linked to the person to whom the record refers or from whom the sample was obtained. Depending on the circumstances, the code may be known only to the person concerned or the key to the code may be held by the person who collected the material (such as the physician of the person concerned), by the repository where the record or sample is held, and/or by an investigator who is using the material in a study. iii. Linked, double-coded record or sample: Similar to a linked, coded record or biological sample except that two different codes are used for each record or sample; one key, which connects the codes on different samples and records (and allows data derived from analysing samples to be compared to data from records), is created by the repository and used by investigators, while a separate coding system that links each record or sample to the person concerned is held by a third party (such as the physician who submitted the record or sample) and is not available to the investigator. Although double-coding makes linking samples or records to a particular person much more difficult, the existence of the codes means that such linkage might occur, either accidentally or through diligent effort.

Immunity	The body's ability to protect itself against infection and disease or other unwanted biological invasion, and is related to the function of the immune system..Immunization is the process whereby a person is made immune or resistant to an infectious disease, typically by the administration of a vaccine. Vaccines stimulate the body's own immune system to protect the person against subsequent infection or disease.
Immunogenic	Capable of eliciting an immune response.
Impartial witness	A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent documentation.
In vitro	The technique of carrying out an experiment in an artificial environment outside a living organism. Generally, it is performed in glass or plastic vessels in a laboratory.
Inclusion criteria: (see also 'Exclusion criteria')	A set of conditions that must be met in order to participate in a clinical trial. In other words - the standards used to determine whether a person may be allowed to participate in a clinical trial. The most important criteria used to determine appropriateness for clinical trial participation include age, sex, the type and stage of a disease, treatment history, and other medical conditions. See *Exclusion criteria* .
Indicator	A measurable quantity which 'stands in' or substitutes, in some sense, for something less readily measurable. From Sage Dictionary
Inducement	Something offered to prospective participants in return for taking part in research; common examples include money and food. Inducements are common in research, and appropriate so long as they are not undue. Potential inducements and other benefits of research should be considered on a case by case basis by research ethics committees who can take account of the individual nature of each study and geographical area. From Global Health Reviewers Glossary (http://globalhealthreviewers.tghn.org/resources/glossary/)
Innovative therapy	Innovations in clinical practice which include the wide range of new diagnostic or therapeutic methods which are aimed at improving health outcomes beyond those of existing methods, but which have not yet been fully assessed for safety and/or efficacy. The spectrum of innovations ranges widely from minor variations of existing methods, or extension of existing methods to new indications, through to completely novel technologies.

Intervention	A defined set of research activities that are implemented to achieve specified outcomes in a target population
Interventional or intervention study	An epidemiological study based on an intervention; synonymous with “experimental study”. Such studies test the effects of interventions (often termed "treatments" in the technical literature, not to signify that they are therapeutic but that they change the circumstances) which are assigned to subjects in a population following a study protocol. For example, an intervention would be a screening test for early recognition and management of a disease to be compared with no screening or with screening with lesser frequency; or a treatment could be a vaccine to prevent a disease of viral origin to be compared with no vaccine or a different vaccine. Whenever possible, subjects are assigned interventions at random (a randomized controlled trial). Random allocation means that, other than the intervention itself, all possibly relevant factors (both those already known to affect the outcomes being studied and those not yet identified) are on average equally distributed between groups receiving the different modalities; consequently, assuming the sample size is large enough to yield statistically significant results, random allocation ensures that any observed difference in outcomes can be confidently regarded as a real effect of the intervention.
Intrauterine Device (IUD)	A small, T-shaped plastic birth-control device wrapped in copper or containing hormones, placed in the uterus. It stays effective for at least five years and is the most widely used contraceptive method worldwide. **IUDs do not protect against STI/HIV.**
Investigator's brochure	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human subjects.
IRB	Institutional review board
Justice	Refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her. In the ethics of research involving human subjects the principle refers primarily to distributive justice, which requires the equitable distribution of both burdens and the benefits of participation in research.
Knowledge, attitude and practice (KAP) survey	An assessment of the knowledge, attitudes, and practices of a community or group of individuals at one point in time, usually with respect to a health or health-related topic.

Malaria	Malaria is a disease which can be transmitted to people of all ages. It is caused by parasites of the species *Plasmodium* that are spread from person to person through the bites of infected female Anopheles mosquitoes. In the human body, the parasites multiply in the liver, and then infect red blood cells. Symptoms of malaria include fever, headache, and vomiting, and usually appear between 10 and 15 days after the mosquito bite. If not treated, malaria can quickly become life-threatening by disrupting the blood supply to vital organs. In many parts of the world, the parasites have developed resistance to a number of malaria medicines. Malaria is both preventable and curable. Key interventions to control malaria include: prompt and effective treatment with artemisinin-based combination therapies; use of insecticidal nets by people at risk; and indoor residual spraying with insecticide to control the vector mosquitoes. If not treated promptly with effective medicines, malaria can cause severe illness that is often fatal. There are four types of human malaria – *Plasmodium falciparum, P.vivax, P.malariae,* and *P.ovale,* The most deadly type of malaria infection is *P.falciparum* , which together with *P. vivax* , is also the most common. Approximately, 40% of the world's population, mostly those living in the world's poorest countries, are at risk of malaria. Every year, more than 500 million people become severely ill with malaria. Most cases and deaths are in sub-Saharan Africa.
Microbicides	Any compound or substance whose purpose is to kill microbes e.g. bacteria or viruses. In the context of sexually transmitted infections, microbicides are compounds that can be applied inside the vagina or rectum to protect against sexually transmitted infections (STIs) including HIV. They can be formulated as gels, creams, films, or suppositories. Microbicides may or may not have spermicidal activity (contraceptive effect). At present, an effective microbicide against HIV is not available.
Minimal risk	In this expression 'risk' is taken in its common meaning of a possible but not certain adverse effect (on health). Minimizing risk implies reducing to the feasible minimum the number and magnitude of such possible effects as well as the probability that they will occur. A study is often said to involve "minimal risk" when the potential harms involved are comparable to those as experienced in "ordinary life" by a person of a given age and gender or by an apparently healthy person undergoing routine medical surveillance.

Monitoring	In the context of a clinical trial, monitoring is the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s).
Multicentre trial	A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.
NGO	Acronym for Non-Governmental Organizations and is used to encompass the wide range of organisations that can be broadly characterised as 'non-government', including Community-Based Organisations (CBOs), Faith-Based Organisations (FBOs) and organisations of affected communities.
Non-identifiable material (see also Identifiable material)	Includes unlinked records or biological samples that were either collected on an anonymous basis or have been made anonymous (anonymised) in such a way that they do not carry any direct or indirect personal identifier. For these materials, no link is possible between the records or samples and the identity of the person who was the source of the record or sample.
Nuremberg code	The first acknowledged document laying down some of the first principles of research ethics following the war crimes tribunal at Nuremberg. It is considered to be the basic text of modern medical ethics.
Observational study	*see Research design*
Observational study	A research study design in which the research participant and the researcher don't know whether the participant is receiving the intervention being tested or a comparison intervention which could be either a real medical intervention or a placebo. A randomized controlled trial may be blinded if participants in the trial are likely to change their behaviour in a systematic way that may influence the outcome of the study when they are aware of which intervention they receive. The purpose is to avoid unconscious subjective bias affecting the study outcome. The term "masking" is often used instead of "blinding". At the end of the trial, the intervention is unmasked. If problems arise in the course of the trial, specifically any danger to the health or safety of the participants, the trial will also be unmasked to ensure participants' safety.
OHSR	Office of Human Subjects Research

Oral rehydration therapy	A simple, inexpensive and effective treatment for diarrhea-related dehydration. Dehydration from diarrhoea can be prevented by giving extra fluids at home, or it can be treated simply, effectively, and cheaply in all age-groups and in all but the most severe cases by giving patients by mouth an adequate glucose-electrolyte solution. This way of giving fluids to prevent or treat dehydration is called oral rehydration therapy (ORT). ORT, combined with guidance on appropriate feeding practices, is the main strategy recommended by WHO to achieve a reduction in diarrhoea-related mortality and malnutrition in children. ORT is potentially the most significant medical advance of the 20th century.
PAHO, EMRO, SEARO, WPRO, AFRO, EURO	Acronyms for WHO regional offices
Palliative care	An approach that improves the quality of life of patients and their families facing the problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification and assessment and treatment of pain and other problems, physical, psychosocial and spiritual.
Papanicolaou (Pap) test	A routine screening test used for the detection of early cervical abnormalities, namely precancerous dysplastic changes of the uterine cervix, together with viral, bacterial, and fungal infections of the cervix and vagina. Cervical screening is a relatively simple, low cost and non-invasive method. Regular screening for cervical cancer reduces both the mortality and incidence of cervical carcinoma.
Parenteral	Administered or occurring elsewhere in the body that the mouth and alimentary canal.

Phase I, II, III, and IV trials	The CIOMS Guidelines (see above) provide the following useful classification of the phases of clinical trials for vaccine development and for drug development. Vaccine development: Phase I: refers to the first introduction of a candidate vaccine into a human population for initial determination of its safety and biological effects, including immunogenicity. This phase may include studies of dose and route of administration, and usually involves fewer than 100 volunteers. Phase II refers to the initial trials examining effectiveness in a limited number of volunteers (usually between 200 and 500); the focus of this phase is immunogenicity. Phase III trials are intended for a more complete assessment of safety and effectiveness in the prevention of disease, involving a larger number of volunteers in a multicentre adequately controlled study. Drug development: Phase I refers to the first introduction of a drug into humans. Normal volunteer subjects are usually studies to determine levels of drugs at which toxicity is observed. Such studies are followed by dose-ranging studies in patients for safety and, in some cases, early evidence of effectiveness. Phase II investigation consists of controlled clinical trials designed to demonstrate effectiveness and relative safety. Normally, these are performed on a limited number of closely monitored patients. Phase III trials are performed after a reasonable probability of effectiveness of a drug has been established and are intended to gather additional evidence of effectiveness for specific indications and more precise definition of drug-related adverse effects. This phase includes both controlled and uncontrolled studies. Phase IV trials are conducted after the national drug registration authority has approved a drug for distribution or marketing. These trials may include research designed to explore a specific pharmacological effect, to establish the incidence of adverse reactions, or to determine the effects of long-term administration of a drug. Phase IV trials may also be designed to evaluate a drug in a population not studied adequately in the pre-marketing phase (such as children or the elderly) or to establish a new clinical indication for a drug. Such research is to be distinguished from marketing research, sales promotion studies, and routine post-marketing surveillance for adverse drug reactions in that these categories ordinarily need not be reviewed by ethical review committees.
PI	Principal investigator
Placebo	In the context of research, placebo is a substance or procedure which a patient accepts as a medicine or therapy but which actually has no specific therapeutic activity for his condition.
Placebo-control study	see Research design
Placebo-control study	A research design in which the use of a "dummy" or inert intervention is used as a comparator in a control arm of the study in order to eliminate bias.

Plasmodium falciparum	**see malaria**
Plasmodium vivax	**see malaria**
Polygenic	Pertaining to or determined by several different genes
Population-proportional sampling	Approach to selection of clusters or households to be sampled, whereby more populous sections of the study area are allocated proportionately more clusters or households
Post traumatic Stress Disorder (PTSD)	A psychological condition that can result from experiencing, witnessing, or participating in an overwhelmingly traumatic (frightening) event. Symptoms may include nervousness, fearfulness, poor concentration, muscle tremor and hyperventilation. Though its symptoms can occur soon after the event, the disorder often surfaces several months or even years later.
Prophylactic measures	Measures taken to defend against or prevent disease
Prospective study	*see Research design*
Prospective study	A study in which data on exposures and disease outcome are collected as the events occur, unlike a retrospective study (see Retrospective study).
Public Health	Public health refers to all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases. Thus, public health is concerned with the total system and not only the eradication of a particular disease.
Quality assurance	System of procedures, checks, audits and corrective actions to ensure that all testing, sampling, analysis, monitoring and other technical and reporting activities are of the highest achievable quality.
Quality control	The supervision and control of all operations involved in a process usually involving sampling and inspection, in order to detect and correct systematic or excessively random variations in quality.

Quinacrine hydrochloride	A dihydrochloride drug which has been used in the past as an antimalarial and for female sterilization. Various research groups (but not WHO) have attempted to exploit the sclerosing property of the antimalaria drug quinacrine for sterilization. The usual procedure is for pellets of the drug to be placed in the uterus by means of a special inserter. The pellets have been inserted in varying doses, with one, two, or three insertions, and at different times in the menstrual cycle. More than one insertion is apparently more effective than just one but there are not enough data on efficacy of the method, dosage levels needed, or number of insertions that give the best results with fewest adverse effects. One study on efficacy conducted in 1992 showed a gross failure rate of 3.1% at 12 months following quinacrine instillations, with 40% of the patients having no period for six months, though 93% had resumed menstruation within one year. Although some 70 000 women have been given quinacrine for sterilization, the safety of the method remains unproven. WHO has recommended that clinical studies with quinacrine should not be undertaken until proper toxicological testing has been done. Progress in Reproductive Health Research No. 36 part 1, 1995 http://www.who.int/reproductive-health/hrp/progress/36/news36_1.en.html
Race	A group of persons connected by common descent or origin.
Randomisation	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias.
Randomised control study	In a RCT, participants are randomly assigned either to an intervention group (e.g. a drug treatment) or to a control group (e.g. a placebo group). Both groups are followed over a specific period of time and the effects of the intervention on specific outcomes (dependant variables) defined at the outset are analysed (e.g. serum cholesterol levels, death rates, remission rates)
Randomised control trial	*see Research design*
RCT	Randomised control trial or randomised controlled trial
REC	Research ethics committee
Recall bias	In psychology, recall bias is a type of systematic bias which occurs when the way a survey respondent answers a question is affected not just by the correct answer, but also by the respondent's memory. This can affect the results of the survey.

Register and registry	A register is an ordered collection of records, for instance of births or of deaths. A registry is an organized system to develop, maintain and use one or more registers, for example a national registry may keep the registers of births and deaths. By extension the institution responsible for the system is also often called a registry (e.g., a cancer registry). A clinical trials registry registers clinical trials.
Regulatory authorities	Bodies having the power to regulate. In the ICG GCP guideline the expression Regulatory Authorities includs the authorities that review submitted clinical data and those that conduct inspections. These bodies are sometimes referred to as competent authorities.
Research (with human beings)	Any social science, biomedical or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings (i) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly, or through alteration of their environment, or (ii) become individually identifiable through investigators' collection, preparation, or use of biological material or medical or other records.i**. Clinical research** Is often conducted with patients in a medical setting, such as a hospital, and is designed to obtain better information on the natural history or pathogenesis of a condition that may lead to improved strategies for diagnosis, treatment or prevention of a disease.ii. **Epidemiological research**: Usually involves population-based investigations, which may be cross-sectional surveys of selected populations (case-control studies) or all members of a community, or may involve longitudinal study of a population over time (cohort studies). Such research is conducted to obtain an improved understanding of the natural history of a disease or to identify factors that increase or decrease the risk of disease in individuals. Often such investigations involve the study of large populations and they may be observational or interventional in nature. The aim is to identify strategies for the better prevention or treatment of disease, through an improved understanding of risk factors for disease or for progression of disease.iii**. Social and behavioural research**: Is often a component of epidemiological research and focuses on the study of behavioural and social factors that may modify risk of disease in individuals or in populations. Such research may involve the collection of sensitive information about a person and their lifestyle (e.g. sexual behaviour). While some forms of research may only involve observation others may involve studying or testing ways of changing behaviour or social circumstances.iv. **Intervention studies:** Are conducted to evaluate the impact of specific interventions on the prevention of disease, often in the context of community-based intervention trials, or in modifying the clinical course of disease, often in the context of clinical trials. Such research may provide the basis for policy decisions and priority setting. Intervention studies usually involve the comparison of different treatment or prevention strategies in which the current intervention method is

Research design	A formalised and usually systematic plan to collect data that will inform a research hypothesis.
Research Ethics Committee (REC) (can also be known as Ethics Committee, Ethical Review Board, Institutional Review Board (IRB), Human Research Ethics Committee(HREC)	Group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles. Research ethics committees review proposed studies with human participants (or samples deriving from them) to ensure they conform to international and locally accepted international guidelines, monitor studies once they have begun and, where relevant, take part in follow-up action and surveillance after the end of research. Committees have the authority to approve, reject or stop studies, or require modifications to research protocols.
Research protocol	A document written by the investigator(s) which should typically contain a project summary; general information; background rationale; references and literature review; study goals and objectives; study design; methodology; safety considerations; follow-up; data management considerations and statistical analysis; quality assurance; expected outcomes of the study; dissemination of results and publication policy; duration of the project; problems anticipated; project management structure and process; ethical considerations; informed consent documents; funding organization(s); collaborations; and qualifications of senior researchers.
Resection	The surgical removal, fully or partially, of any tissue or organ.
Respect for persons	Incorporates at least two fundamental ethical considerations, namely: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two seperate moral requirements to acknowledge autonomy and the requirement to protect those with diminished autonomy. (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978) Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.)

Retrospective study	A study in which data on exposures and disease outcome are collected some time after the event, unlike a prospective study (see Proposective study). Also refers to an observational study design in which the investigators study present and past events
Retrospective study	see Research design
Revision	Requirement by the research ethics committee to alter (revise) the protocol in some specified way prior to approval or additional review by the committee.
RHR	Reproductive health research
Risk (in research context)	The probability that an event, favourable or adverse, will occur within a defined time interval. Although often contrasted to benefit (as in a "risk/benefit ratio"), the term "potential harm" is better for that context, leaving "risk" in its formal epidemiological sense to express the probability of a (typically adverse) event or outcome. (CIOMS Epidemiological guidelines)
Risk factor	Any attribute, characteristic or exposure of an individual, which increase the likelihood of developing a disease or injury.
Sample	A sample is a subset of a population that is used to represent the entire group as a whole.
Sample size	Sample size is the number of observations used for calculating estimates of a given population.
SARS (Severe acute respiratory syndrome)	"A viral respiratory illness that may lead to death, caused by a coronavirus called SARS-associated coronavirus (SARS CoV). Initial symptoms are flu-like, including a fever, and usually appear 2–10 days following exposure, but can appear up to 13 days later. In most cases symptoms appear within 2–3 days. SARSCoV is believed to be an animal virus that crossed the species barrier to humans recently when ecological changes or changes in human behaviour increased opportunities for human exposure to the virus and virus adaptation, enabling human-to-human transmission . By July 2003, the international spread of SARS-CoV resulted in 8098 SARS cases in 26 countries, with 774 deaths. The epidemic caused significant social and economic disruption in areas with sustained local transmission of SARS and on the travel industry internationally in addition to the impact on health services directly". (http://www.who.int/csr/resources/publications/WHO_CDS_CSR_ARO_2004_1/en/index.html)

Schizophrenia	A mental disorder, characterized by profound disruptions in thinking, affecting language, perception, and the sense of self. It often includes psychotic experiences, such as hearing voices or delusions. It can impair functioning through the loss of an acquired capability to earn a livelihood, or the disruption of studies. Schizophrenia typically begins in late adolescence or early adulthood. Most cases of schizophrenia can be treated, and people affected by it can lead a productive life and be integrated in society.
Sclerosing agent	A substance that causes a marked tissue irritation and/or thrombosis with subsequent local inflammation and tissue necrosis.
Selection bias	Selection bias is a statistical bias in which there is an error in choosing the individuals or groups to take part in a scientific study. It is sometimes referred to as the selection effect. The term "selection bias" most often refers to the distortion of a statistical analysis, resulting from the method of collecting samples. If the selection bias is not taken into account then certain conclusions drawn may be wrong.
Serious adverse event (SAE) or Serious adverse drug reaction (serious ADR)	Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.
Sexually transmitted infections (STIs)	Infections that are spread primarily through person-to-person sexual contact. There are more than 30 different sexually transmissible bacteria, viruses and parasites. The most common conditions they cause are gonorrhoea, chlamydial infection, syphilis, trichomoniasis, chancroid, genital herpes, genital warts, human immunodeficiency virus (HIV) infection and hepatitis B infection. Several, in particular HIV and syphilis, can also be transmitted from mother to child during pregnancy and childbirth, and through blood products and tissue transfer.
Single-blind study	Typically, a study designed in which the investigator, but not the participant, knows the treatment assignment.
Single-blind study	*see Research design*
Spatial sampling	Approach to selection of clusters or households to be sampled, whereby clusters and/or households are allocated proportionately to surface area within the study area. Alternative to population-proportional sampling (ODI/HPN paper 52, 2005, Checchi and Roberts)

Specificity in surveillance	A measure of how infrequently a system detects false positive health events, i.e. the number of individuals identified by the system as not being diseased divided by the total number of all persons who do not have the disease (Protocol for the assessment of national communicable disease surveillance and response systems: Guidelines for the assessment teams).
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of research.
Squamous intraepithelial lesion (SIL)	A general term for the abnormal growth of squamous cells on the surface of the cervix. The changes in the cells are described as low grade (LSIL) or high grade (HSIL), depending on how much of the cervix is affected and how abnormal the cells are. HSIL is considered a significant precancerous lesion, whereas low-grade SIL (LSIL) is considered a much more benign lesion since most of these lesions regress
Standard	A set of rules for ensuring high quality performance and a common language, that establish parameters against which achievements can be benchmarked .
Standard operating procedures (SOPs)	Detailed, written instructions to achieve uniformity of the performance of a specific function. A research ethics committee, for example, should have SOPs to guide their functioning.
STDs	Sexually transmitted dieseases
Stem cells	Unspecialized cells that renew themselves for long periods through cell division and have the remarkable potential to develop into many different cell types in the body. Typically they serve as the repair system for the body and are found in the bone marrow in adults and can be obtained from the umbilical cord. Under certain physiologic or experimental conditions, they can be induced to become cells with special functions such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.
Stigma	A process of producing and reproducing inequitable power relations, where inequalities in society are created and sustained through negative attitudes towards a group of people on the basis of particular attributes such as their HIV status, gender, sexuality or behaviour.
Structured interview	An interview, generally with only one person, in which the questions are pre-defined and asked in a specific order with the interviewer, or assistant, writing down the answers.

Subject identification code	A unique identifier assigned by the investigator to each trial subject to protect the subject's identity and used in lieu of the subject's name when the investigator reports adverse events and/or other trial related data.
Surveillance	In the context of public health, the ongoing systematic collection, collation, analysis and interpretation of data; and the dissemination of information to those who need to know in order that action may be taken.
Systematic random sampling	A sampling design whereby an individual sampling frame of households is established, and households to be sampled are selected using a constant sampling step (i.e. every nth household) (ODI/HPN paper 52, 2005, Checchi and Roberts).
Tamoxifen	An anti-oestrogenic drug, tamoxifen has been used for almost two decades as the first-line endocrine therapy for postmenopausal women with advanced metastatic breast cancer. Tamoxifen is also used as adjuvant therapy in patients with breast cancer and is being tested for use as a preventive agent. There is conclusive evidence that tamoxifen reduces the risk for contralateral breast cancer in women with a previous diagnosis of breast cancer.
TDR	Tropical Disease Research (WHO Department)
Teratogen	An agent, such as a virus, drug or radiation that may cause malformation of an embryo or fetus.
Tetanus	A disease caused by the bacterium *Clostridium tetani* . It is characterized by muscle spasms, initially in the jaw muscles. As the disease progresses, mild stimuli may trigger generalized tetanic seizure-like activity, which contributes to serious complications and eventually death unless supportive treatment is given. Tetanus can be prevented by the administration of tetanus toxoid, which induces specific antitoxins. To prevent maternal and neonatal tetanus, tetanus toxoid needs to be given to the mother before or during pregnancy, and clean delivery and cord care needs to be ensured.
The Declaration of Helsinki	This declaration by the World Medical Association (WMA) serves as a statement of ethical principles to provide guidance to physicians and others involved in medical research with human beings and identifiable human material or identifiable data. It is one of the most widely known and accepted guideline documents for research ethics. Amendments and clarifications have been made to the original 1964 Declaration and the WMA stresses that the most recent version is the only one in effect.

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human use (ICH)	A project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry to discuss scientific and technical aspects of product registration. The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to facilitate a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines while maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.
Triage	The process of selecting for care or for treatment those of highest priority or, when resources are limited, those who are more likely to benefit.
Trial	A generic term that in a clinical context denotes a research activity involving the administration of an intervention to humans to evaluate its safety and efficacy.
Trichomonas vaginalis (T. vaginalis)	A sexually transmitted infection (STI) and the most common pathogenic protozoan infection of women in industrialized countries.
Tubal occlusion	A surgical procedure blocking the fallopian tubes and therefore causing a woman's permanent fertility.
Tuberculosis (TB)	Tuberculosis, or TB, is an infectious bacterial disease caused by *Mycobacterium tuberculosis* , which most commonly affects the lungs. It is transmitted from person to person via droplets from the throat and lungs of people with the active respiratory disease. In healthy people, infection with *Mycobacterium tuberculosis* often causes no symptoms, since the person's immune system acts to “wall off” the bacteria. The symptoms of active TB of the lung are coughing, sometimes with sputum or blood, chest pains, weakness, weight loss, fever and night sweats. Tuberculosis is treatable with a six-month course of antibiotics
UNAIDS	United Nations Joint Programme on AIDS
Validity	In scientific research design and experimentation, validity refers to whether a study is able to scientifically answer the questions it is intended to answer.
Vasectomy	Male sterilization by removal of sections of each vas deferens
Vertical transmission	Spread of infection from the mother directly to the offspring during pregnancy, birth or breastfeeding.

Vulnerable (research) participants	Individuals whose willingness to volunteer in a clinical trial [or other type of research] may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental, and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, persons in nursing homes, unemployed or impoverished persons, patients in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent. This list may not be exhaustive as there may be circumstances in which other groups are considered vulnerable, women for example, in an orthodox patriarchical society.
Whistleblowing	Reporting misconduct of an organization, such as violations of the law, corruption, fraud, health/safety violations etc. The term is usually used describing the action taken by an employee when making such misconduct public, especially within a business or government agency.