

Glossary of Clinical Trial Terms

ADVERSE REACTION: (Adverse Event): Also known as side effects, adverse reactions include any undesired actions or effects of the experimental drug or treatment. Experimental treatments must be evaluated for both immediate and long-term side effects.

APPROVAL: A drug, device or biologic must be approved by a country's regulatory agency before it can be marketed. The approval process involves several steps including pre-clinical (animal) studies, clinical trials for safety and efficacy, filing of a New Drug Application (NDA) in the United States or Marketing Authorization Application (MAA) in Europe by the manufacturer, regulatory agency review of the application, and agency approval/rejection of application.

ARM: Any of the treatment groups in a clinical trial. Most randomized trials have two "arms," but some have three "arms," or even more.

BASELINE: Baseline information is gathered at the beginning of a study from which variations found in the study are measured. Baseline can also be described as a known value or quantity with which an unknown is compared when measured or assessed. Safety and efficacy of a drug are often determined by monitoring changes from the baseline values.

BIAS: When a point of view prevents impartial judgment on issues relating to the subject of that point of view. In clinical studies, bias is controlled by blinding and randomization.

BLIND, BLINDED or BLINDING: A clinical trial is "blinded" if the participants are unaware on whether they are in the experimental or control arm of the study. Blinding may also be extended to the investigators so that their patient observations are less likely to be biased by their awareness of the treatment the patient is receiving.

CASE CONTROL STUDY: A scientific study that compares a group of people with a disease (such as leukemia) to a similar group of people without that disease. This type of study compares the levels of exposure (for example, radiation or chemical) each group had before appearance of the disease.¹

CLINICAL: Pertaining to or founded on observation and treatment of human participants or patients, as distinguished from theoretical or basic science.

CLINICAL INVESTIGATOR: A medical researcher in charge of carrying out a clinical trial's protocol.²

CLINICAL RESEARCH ASSOCIATE (CRA): Person employed by the study sponsor or clinical research coordinator to monitor a clinical trial at one or more participating sites. The CRA is responsible for ensuring all clinical studies are conducted according to study protocol, within regulations and ICH guidelines.³

¹ Centers for Disease Control and Prevention. NIOSH Energy-Related Health Research Program, Glossary. Available at: <http://www.cdc.gov/niosh/2001-133o.html>. Last accessed 10.24.07.

² Association of Clinical Research Organizations. Glossary of Clinical Trial Terms. Available at: <http://www.acrohealth.org/glossary.php>. Last accessed 10.24.07.

³ Clinical Data Interchange Standards Consortium. Glossary of Terms. Available at: http://www.cdisc.org/glossary/V6_Glossary2007.pdf. Accessed 01.09.08.

All definitions came from (<http://www.clinicaltrials.gov/ct/info/glossary>) unless otherwise noted.

CLINICAL RESEARCH COORDINATOR (CRC): Site administrator for the clinical trial who is responsible for coordinate administrative activities between field and home offices staff, such as the collection of essential documents, distribution of supplies and site selection. Also called research, study or health care coordinator, data manager, research nurse or protocol nurse.⁴

CLINICAL TRIAL: Clinical trials, also known as clinical studies, test potential treatments in human volunteers or patients to see whether they should be further investigated or approved for wider use in the general population. A treatment could be a drug, medical device, or biologic, such as a vaccine, blood product, or gene therapy. Potential treatments, however, must first be studied in laboratory models or animals to determine its safety before they can be tried in people. Treatments having acceptable safety profiles for the disease or condition and showing the most promise are then moved into clinical trials. Clinical trials are an integral part of new product discovery and development, and are required by all regulatory agencies (e.g., the Food and Drug Administration (FDA) in the United States), before a new product can be brought to the market.

COMMUNITY-BASED CLINICAL TRIAL (CBCT): A clinical trial conducted primarily through primary care physicians rather than researchers at academic facilities.

COMPASSIONATE USE: A method of providing experimental therapeutics prior to final regulatory agency approval for use in humans. This procedure is used with very sick individuals who have no other treatment options. Often, case-by-case approval must be obtained by the patient's physician from the regulatory agency for "compassionate use" of an experimental drug or therapy.

CONFIDENTIALITY REGARDING TRIAL PARTICIPANTS: Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical information. The trial participants' consent to the use of records for data verification purposes must be obtained prior to the trial. The Informed Consent Document will explain how personal health information and study data will be used in accordance with pertinent data protection laws and regulations.

CONTRACT RESEARCH ORGANIZATION (CRO): A commercial organization contracted by a research and development organization to perform one or more research-related functions.⁵

CONTRAINDICATION: A specific circumstance in which the use of certain treatments are not allowed usually because they could be harmful or fatal.

CONTROL GROUP: A control is the standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo.

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West Coast Clinical Trials. Glossary. Available at: <http://www.wcctrials.com/glossary.HTM>. Last accessed 10.24.07.

⁵ Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

All definitions came from (<http://www.clinicaltrials.gov/ct/info/glossary>) unless otherwise noted.

CONTROLLED TRIALS: A control is a standard against which experimental observations may be evaluated. In a controlled clinical trial, one group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.

CROSSOVER TRIAL: A clinical trial in which all participants receive both treatments, but at different times. At a predetermined point in the study, one group is switched from the experimental treatment to the control treatment (standard treatment), and the other group is switched from the control to the experimental treatment.⁶

DATA SAFETY MONITORING BOARD (DSMB): A committee, independent of the sponsor, composed of clinical research experts that reviews trial data while a clinical trial is in progress to ensure that participants are not exposed to undue risk. A DSMB may recommend that a trial be stopped if there are safety concerns or if the trial objectives have been achieved and further continuing the study would not benefit the patients.

DATA SAFETY MONITORING PLAN (DSMP): This plan is meant to assure that each clinical trial has a system for appropriate oversight and monitoring of the conduct of the trial. This oversight ensures the safety of the participants and the validity and integrity of the data.⁷

DECLARATION OF HELSINKI: A series of guidelines adopted by the 18th World Medical Assembly in Helsinki, Finland in 1964. The Declaration addresses ethical issues for physicians conducting biomedical research involving humans. Recommendations include the procedures required to ensure subject safety in clinical trials, including informed consent and Ethics Committee reviews.⁸

DEMOGRAPHIC DATA: The characteristics of participant group or populations. This could include data on race, age, sex and medical history, all of which can be relevant to the clinical trial study findings.⁹

DEVICE: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part or accessory, that is used to diagnose, cure, treat, or prevent disease. A device does not achieve its intended purpose through chemical action or metabolism in the body.¹⁰

DIAGNOSTIC TRIALS: Refers to trials that are conducted to find better tests or procedures for diagnosing a particular disease or condition. Diagnostic trials usually include people who have signs or symptoms of the disease or condition being studied.

DOSE-RANGING STUDY: A clinical trial in which two or more doses of an agent (such as a drug) are tested against each other to determine which dose works best and is least harmful.

⁶ Canadian HIV Trials Network. Glossary of Terms. Available at: <http://www.hivnet.ubc.ca/e/clinicaltrials/glossary.html>. Last accessed 10.24.07.

⁷ University of Washington. Glossary. Data and Safety Monitoring Plans (DSMP) Description. Available at: <http://www.washington.edu/research/guide/dsmp.html>. Last accessed 10.24.07.

⁸ Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

⁹ Clinical Data Interchange Standards Consortium. Glossary of Terms. Available at: http://www.cdisc.org/glossary/V6_Glossary2007.pdf. Accessed 01.09.08.

¹⁰ Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

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DOUBLE-BLIND STUDY: A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo or another therapy). Double-blind trials are thought to produce objective results, since the knowledge, expectations and biases of the doctor and the participant about the experimental drug or treatment do not affect the outcome.

DRUG-DRUG INTERACTION: A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

EFFECTIVENESS: Whether a drug achieves its desired effect in the real world.¹¹

EFFICACY: (Of a drug or treatment) the ability of a drug or treatment to produce a beneficial result. A drug demonstrates efficacy if it is effective at the dose tested against the illness for which it is prescribed.

ELIGIBILITY CRITERIA: Summary criteria for participant selection; includes inclusion and exclusion criteria.

EMPIRICAL: Based on observation or experience, not experimental data.

ENDPOINT: Overall outcome that the protocol is designed to evaluate.

EPIDEMIOLOGY: The branch of medical science that deals with the study of incidence, distribution and control of a disease in a population.

ETHICS COMMITTEE: See institutional review board or "IRB" definition below

EUROPEAN MEDICINES AGENCY (EMA): The European regulatory agency responsible for the scientific evaluation of applications for European marketing authorization for medicinal products (centralized procedure). EMA's main mission is to protect and promote public and animal health, through the evaluation and supervision of medicines for human and veterinary use.¹²

EXCLUSION/INCLUSION CRITERIA: The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, pregnancy status, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants to ensure the integrity of the study and to keep them safe.

EXPANDED ACCESS: Refers to any of the regulatory authority procedures, such as compassionate use, parallel track, and treatment Investigational New Drug Application (IND) that distribute experimental drugs to participants who are failing on currently available treatments for their condition and also are unable to participate in ongoing clinical trials.

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Health Canada. Glossary. Available at: http://www.hc-sc.gc.ca/hcs-sss/pharma/nps-snpp/securit/guide_gloss_e.html. Last accessed 10.24.07.

¹² European Medicines Agency. Overview. Available at <http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm>. Last accessed 01.09.08.

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EXPERIMENTAL/INVESTIGATIONAL DRUG: A drug that has been authorized for use in a clinical trial but has not been granted marketing approval as a treatment for a particular use.

FIRST-IN-HUMAN/MAN STUDY: A clinical trial where a medical procedure or medicinal product, previously developed and assessed through laboratory model or animal testing, or through mathematical modeling is tested on human subjects for the first time.¹³

FOOD AND DRUG ADMINISTRATION (FDA): The U.S. Department of Health and Human Services agency responsible for ensuring the safety and effectiveness of all drugs, biologics, vaccines, and medical devices. The FDA also works with the blood banking industry to safeguard the nation's blood supply.

GENERIC DRUGS: A medicine with the same active ingredient, but not necessarily the same inactive ingredients, as a brand-name drug. A generic drug may be marketed only after the original drug's patent has expired.¹⁴

HIPAA: The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. It also addresses the security and privacy of health data. All clinical trial data and activities performed by covered entities must comply with HIPAA regulations.

HUMAN SUBJECT: A patient or healthy person participating in a research project.¹⁵

HYPOTHESIS: A theory, supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation.

INFORMED CONSENT: Informed consent is the verification of a person's willingness to participate in a research project. Prior to enrollment into a clinical trial, researchers inform participants about all relevant study details. Participants are provided an informed consent document that details all the important study information including its purpose, duration, risks, potential benefits, required procedures, and key contacts, and they will be asked to sign this document if they agree to participate in the trial. The informed consent document is not a contract. Participation in the clinical trial is voluntary and the participant may withdraw from the trial at any time without penalty or loss of benefits to which he/she is otherwise entitled. The research team actively maintains informed consent throughout the trial by providing the participant with any new or developing information.

INFORMED CONSENT DOCUMENT: A document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant will be asked to sign this document if they agree to participate in the trial. The informed consent document is not a contract. Participation in the clinical trial is voluntary and the participant may withdraw from the trial at any time without penalty or loss of benefits to which he/she is otherwise entitled.

¹³ The Free Dictionary. Available at: <http://encyclopedia.thefreedictionary.com/First-in-man+study>

¹⁴ Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

¹⁵ Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

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INSTITUTIONAL REVIEW BOARD (IRB): A committee of physicians, statisticians, researchers, community advocates, and others that ensures that a clinical trial is ethical and that the rights of study participants are protected. Every institution that conducts or supports biomedical or behavioral research involving human participants must, by federal regulation, have an IRB that approves and periodically reviews the research in order to protect the rights of human participants.

INTENT TO TREAT: Analysis of clinical trial results that includes all data from participants in the groups to which they were randomized even if they never received the treatment.

INTERVENTION NAME: The generic name of the experimental treatment being studied.

INTERVENTIONS: Primary experimental treatments being studied. Types of treatments may include drug, gene transfer, vaccine, behavior, device, or procedure.

INVESTIGATIONAL NEW DRUG APPLICATION (IND): The petition through which a drug sponsor requests the FDA to allow human testing of a new drug, antibiotic drug, or biological drug in a clinical investigation. This includes an application for a biological product used *in vitro* for diagnostic purposes.¹⁶

IN VIVO: Testing or action inside an organism, such as a human subject or patient.¹⁷

IN VITRO: Testing or action outside an organism (e.g. inside a test tube or culture dish.)¹⁸

MARKETING AUTHORIZATION APPLICATION (MAA): An application submitted by a sponsor to the EMEA for approval to market a new drug (a new, non-biological molecular entity) for human use in Europe.¹⁹

META-ANALYSIS: Systematic methods that use statistical techniques for combining results from similar studies to obtain a quantitative estimate of the overall effect of a particular intervention or variable on a defined outcome. This type of analysis is typically hypothesis generating.²⁰

MULTICENTER TRIAL: Clinical trial conducted according to a single protocol but at more than one site, and, therefore, carried out by more than one investigator.²¹

MULTIPLE-RISING DOSE STUDY: see dose ranging study above.

NATIONAL INSTITUTES OF HEALTH (NIH): Agency within the Department of Health and Human Services that funds research, conducts studies, and funds multicenter national studies.²²

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Food and Drug Administration. Center for Drug Evaluation and Research. Drug Applications. Available at http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm#Introduction. Last accessed 01.09.08

¹⁷ US Environmental Protection Agency. Glossary I. Available at: <http://www.epa.gov/OCEPAterms/iterns.html>. Last accessed 10.24.07.

¹⁸ US Environmental Protection Agency. Glossary I. Available at: <http://www.epa.gov/OCEPAterms/iterns.html>. Last accessed 10.24.07.

¹⁹ European Medicines Agency. Overview. Available at <http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm>. Last accessed 01.10.08.

²⁰ National Library of Medicine. National Institutes of Health. HTA 101: Glossary. Available at: <http://www.nlm.nih.gov/nichsr/hta101/ta101014.html>. Last accessed 10.24.07.

²¹ Trimanos. Adverse Event Terms. Available at: <http://www.trimanos.com/sys/terms.asp>. Last accessed 10.24.07.

²² Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

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NEW DRUG APPLICATION (NDA): An application submitted by a sponsor to the FDA for approval to market a new drug (a new, non-biological molecular entity) for human use in interstate commerce in the United States.²³

OBSERVATIONAL STUDY: An epidemiologic study that does not involve any intervention, experimental or otherwise. Such a study may be one in which nature is allowed to take its course, with changes in one characteristic being studied in relation to changes in other characteristics. Analytical epidemiologic methods, such as case-control and cohort study designs, are properly called observational epidemiology because the investigator is observing without intervention other than to record, classify, count, and statistically analyze results.²⁴

OFF-LABEL USE: A drug prescribed for conditions other than those approved by a country's regulatory agency.

OFFICE FOR HUMAN RESEARCH PROTECTIONS (OHRP): The Office for Human Research Protections (OHRP) supports, strengthens and provides leadership to the nation's system for protecting volunteers in research that is conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP provides clarification and guidance to research institutions, develops educational programs and materials, and promotes innovative approaches to enhancing human subject protections. ²⁵

OPEN-LABEL TRIAL: A clinical trial in which doctors and participants know which treatment is being administered.

ORPHAN DRUGS: A drug category that refers to medications used to treat rare diseases and conditions. Orphan drug status, provides a manufacturer specific incentives to develop and bring such treatments to market.

OUTCOMES TRIAL/STUDY: An outcomes trial evaluates the effect of a treatment on patients. Treatments may include medications or other therapies and outcomes may include changes in disease status, morbidity or mortality.

P-VALUE: A p-value demonstrates the likelihood that sample data do not adequately represent the population from which they were drawn.²⁶ The accepted standard for a statistically significant p-value is <0.05 , meaning that the likelihood that the result could occur by random chance is less than 5 in a hundred.

PARALLEL STUDY: A parallel designed clinical trial compares the results of a treatment on two separate groups of patients. The sample size calculated for a parallel design can be used for any study where two groups are being compared.²⁷

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National Library of Medicine. National Institutes of Health. HTA 101: Glossary. Available at: <http://www.nlm.nih.gov/nichsr/hta101/ta101014.html>. Last accessed 10.24.07.

²⁴ Diabetes Monitor. Glossary of terms. Available at: http://www.diabetesmonitor.com/dictionary/glossary_nhlbi.htm#o. Last accessed 10.24.07.

²⁵ U.S. Department of Health & Human Services. Office for Human Research Protections (OHRP) OHRP Fact Sheet. Available at: <http://www.hhs.gov/ohrp/about/ohrfactsheet.htm>. Last accessed 10.24.07.

²⁶ The Child and Adolescent Health Measurement Initiative. Glossary of Terms. Available at: <http://childhealthdata.org/Content/Glossary.aspx>. Last accessed 10.24.07.

²⁷ Massachusetts General Hospital Mallinckrodt General Clinical Research Center. Definition of Terms. Available at: http://hedwig.mgh.harvard.edu/sample_size/quant_measur/defs.html. Last accessed 10.24.07.

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PEER REVIEW: Review of a clinical trial by independent experts. These experts review the trials for scientific merit, validity, participant safety, and ethical considerations.

PHARMACOLOGY: The study of how drugs interact with living organisms to produce a change in function. Pharmacology deals with how drugs interact within biological systems to affect function.²⁸

PHARMACOKINETICS: The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

PHARMACOVIGILANCE: The science of collecting, monitoring, researching, assessing and evaluating information from healthcare providers and patients on the adverse effects of medications, biological products, herbalism and traditional medicines with a view to identify new information about hazards associated with medicines and preventing harm to patients.²⁹

PHASE 1 CLINICAL TRIAL: Sometimes called dosing studies, these trials may test methods of administering the treatment (e.g. by mouth, injection, etc.) and how often, as well as the safety of the treatment. These trials usually involve a small number of healthy participants (20-80).³⁰

PHASE 2 CLINICAL TRIAL: These trials continue to test the safety of the treatment and evaluate how well the treatment works. Phase 2 studies usually evaluate the treatment in a specific condition. These trials usually involve 100-300 patients.³¹

PHASE 3 CLINICAL TRIAL: These trials compare the new treatment to the current standard of treatment for a specific condition, establishing both efficacy and adverse events. Participants are usually assigned to either receive the new treatment or the current standard. Phase 3 trials typically enroll large numbers of patients (1,000-3,000 or many more) and may be carried out at hospitals and doctors' offices nationwide.³²

PHASE 4 CLINICAL TRIAL: Post-marketing studies to gain a greater understanding of the treatment, including its risks, benefits, and optimal use.³³

PIVOTAL STUDY: A study, usually Phase 3, which presents the data used by regulatory agencies to decide whether to approve a drug. A pivotal study will generally be well-controlled, randomized, and whenever possible, double-blind.³⁴

PLACEBO: A placebo is an inactive pill, liquid or powder that has no treatment value. In clinical trials, a placebo is administered instead of an active drug or experimental treatment to assess the experimental treatment's effectiveness.

PLACEBO CONTROLLED STUDY: A method of drug investigation in which an inactive substance (a placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective than the placebo in treating the condition.

²⁸ The Free Dictionary: Available at: <http://encyclopedia.thefreedictionary.com/PHARMACOLOGY>

²⁹ The Free Dictionary: Available at: <http://encyclopedia.thefreedictionary.com/PHARMACOVIGILANCE>

³⁰ Clinical Data Interchange Standards Consortium. Glossary of Terms. Available at: http://www.cdisc.org/glossary/V6_Glossary2007.pdf. Accessed 01.09.08.

³¹ Clinical Data Interchange Standards Consortium. Glossary of Terms. Available at: http://www.cdisc.org/glossary/V6_Glossary2007.pdf. Accessed 01.09.08.

³² Clinical Data Interchange Standards Consortium. Glossary of Terms. Available at: http://www.cdisc.org/glossary/V6_Glossary2007.pdf. Accessed 01.09.08.

³³ Clinical Data Interchange Standards Consortium. Glossary of Terms. Available at: http://www.cdisc.org/glossary/V6_Glossary2007.pdf. Accessed 01.09.08.

³⁴ Duke Clinical Research Institute. Glossary. Available at: <http://www.dcri.duke.edu/patient/glossary.jsp>. Last accessed 10.24.07.

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PLACEBO EFFECT: A physical or emotional change, occurring after an inactive substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

PRECLINICAL STUDIES: Experiments performed in the laboratory and in animals to study a drug before it is tested in humans.³⁵

PREVENTION TRIALS: Conducted to find better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.³⁶

PRINCIPAL INVESTIGATOR: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator who is the responsible leader of the team may be called the principal investigator.

PROSPECTIVE STUDY: A prospective study identifies subjects, applies a treatment and follows them over time to measure their progress/outcomes relative to a pre-determined set of criteria or endpoints.³⁷

PROTOCOL: A protocol is the study plan on which a clinical trial is based. Each trial is carefully designed to safeguard the health of participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial, the schedule of tests, procedures, medications, dosages, and length of the study.

QUALITY OF LIFE TRIALS (or Supportive Care trials): Refers to trials that explore ways to improve comfort and quality of life for individuals with a chronic illness.

RANDOMIZATION: A method based on chance by which study participants are assigned to different treatment groups. This minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms, thereby avoiding “selection bias.” Randomization allows for researchers to comparably test different treatments in similar groups.

RANDOMIZED TRIAL: A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial.

RESCUE MEDICATION: A quick-relief or fast-acting medication patients in clinical trials may be given besides the investigational drug or control that can alleviate symptoms due to disease or lack of efficacy of the study treatment. It acts quickly to stop symptoms, but the effects are not long lasting.³⁸

³⁵ Available at: http://www.allp.com/LiquiVent/lv_gloss.html. Last accessed 10.24.07.

³⁶ Excel Research Study. Glossary of Terms. Available at <http://www.excelstudy.com/glossary.html>. Last accessed 10.24.07.

³⁷ Medicine Net. MedTerms Dictionary. Available at <http://www.medterms.com/script/main/art.asp?articlekey=24050>. Last accessed 01.10.08.

³⁸ Kids Health for Parents. Rescue Medications. Available at: http://www.kidshealth.org/parent/asthma_basics/dictionary/rescue.html. Last accessed 10.24.07.

All definitions came from (<http://www.clinicaltrials.gov/ct/info/glossary>) unless otherwise noted.

RETROSPECTIVE STUDY: A study in which investigators select groups of patients that have already been treated and analyze data from the events experienced by these patients. These studies are subject to bias because investigators can select patient groups with known outcomes.³⁹

RISK-BENEFIT RATIO: The risk a treatment places on individual participants versus the potential benefits of the treatment. The risk/benefit ratio may differ depending on the condition being treated.

SCREENING TRIALS: Refers to trials which test the best way to detect certain diseases or health conditions.

SIDE EFFECTS: Any undesired actions or effects of a drug or treatment. Experimental drugs must be evaluated for both immediate and long-term side effects.

SINGLE-BLIND STUDY: A study in which subject or patient is unaware of what medication they are taking, while the physician does know.

SPONSOR: A person or an organization that manages and finances a clinical trial.⁴⁰

STANDARD TREATMENT: A treatment currently in wide use by the medical community and approved by a country's regulatory agency considered to be effective in the treatment of a specific disease or condition.

STANDARDS OF CARE: Treatment regimen or management based on state of the art medical care.

STATISTICAL SIGNIFICANCE: The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.

STATISTICIAN: One versed in or engaged in compiling statistics.⁴¹

STUDY ENDPOINT: An outcome used to judge the safety or effectiveness of a treatment.

SURROGATE ENDPOINT: A biomarker or endpoint that is intended to substitute for a clinical endpoint. A surrogate endpoint is expected to predict a clinical endpoint or lack thereof.⁴²

TOXICITY: A treatment-related adverse effect that may be detrimental to the recipient's health. The level of toxicity associated with a treatment will vary depending on the attributes of the treatment itself and the condition the drug is being used to treat.

TREATMENT INVESTIGATIONAL NEW DRUG (IND): It makes promising new drugs available to desperately ill participants as early in the drug development process as possible. Treatment

³⁹ National Library of Medicine. National Institutes of Health. HTA 101: Glossary. Available at: <http://www.nlm.nih.gov/nichsr/hta101/ta101014.html>. Last accessed 10.24.07.

⁴⁰ Meriam Webster Online Dictionary. Sponsor. Available at: <http://www.merriam-webster.com/dictionary/sponsor>. Last accessed 10.24.07.

⁴¹ Meriam Webster Online Dictionary. Statistician. Available at: <http://www.merriam-webster.com/dictionary/sponsor>. Last accessed 10.24.07.

⁴² The Free Dictionary: Available at: <http://encyclopedia.thefreedictionary.com/SURROGATE+ENDPOINT>
All definitions came from (<http://www.clinicaltrials.gov/ct/info/glossary>) unless otherwise noted.

INDs are made available to participants before general marketing begins, typically during Phase 3 studies. To be considered for a treatment IND a participant cannot be eligible to be in the definitive clinical trials.

TREATMENT TRIALS: Refers to trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

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