

BLIND

A condition imposed on an individual (or group of individuals) for the purpose of keeping that individual or group of individuals from knowing or learning of some fact or observation, such as treatment assignment. Also called a "mask"

CONTROLLED CLINICAL TRIAL

A clinical trial involving one or more test treatments, at least one control treatment, and concurrent enrollment, treatment, and follow-up of all patients in the trial.

DATA

(pl. of datum) Factual information, such as measurements, observations, or statistics, which is used as a basis for reasoning, discussion, or calculation.

DOSAGE

A specific quantity of a biologically active compound.

DOSE RANGING

The establishment of the optimal dosage of a new drug by repeated trials of varying dosages

DOUBLE BLIND

1. A procedure in a clinical trial for issuing and administering treatment assignments by code number in order to keep study patients and all members of the clinic staff, especially those responsible for patient treatment and data collection, from knowing the assigned treatments. 2. Any condition in which two different groups of people are purposely denied access to a piece of information in order to keep that information from influencing some measurement, observation, or process.

DOUBLE BLINDED CLINICAL TRIAL

A clinical trial with double-blinded administration of the study treatments.

DRUG TRIAL

A clinical trial in which the test treatments are drugs.

FDA

Food and Drug Administration (a regulatory agency of the United States government, located in Rockville, Maryland). FDA decides which drugs may be approved for sale in the United States.

FOLLOW-UP VISIT

Any patient clinic visit that takes place after the randomization visit for study-related purposes

MATCHING PLACEBO

A pill (capsule or tablet) that is designed to resemble in shape, texture, size, taste, etc., a therapeutically active drug and that is used as the control treatment.

OPEN LABEL TRIAL

1. A clinical trial in which a study physician or study patient decides on the treatment to be administered. Nonrandom clinical trial. 2. A non blinded clinical trial. 3. A clinical trial with an open sequential design.

PARTICIPANT

Study participant.

PHARMACEUTICAL AND REGULATORY AFFAIRS BRANCH

That office at NIAID responsible for coordinating communication with FDA and industry. In particular, PRAB is concerned with drugs under IND status, and with prompt reporting, summary, and analysis of adverse events in NIAID sponsored trials.

PHASE I TRIAL

The first stage in testing a new drug in humans. Performed as part of an approved Investigational New Drug Application under Food and Drug Administration guidelines. The studies are usually done to generate preliminary information on the chemical action and safety of the drug using normal healthy volunteers. Usually done without a comparison group.

PHASE II TRIAL

The second stage in testing a new drug in humans. Performed as part of an approved Investigational New Drug Application under Food and Drug Administration guidelines. Generally carried out on patients with the disease or condition of interest. The main purpose is to evaluate activity, and possibly provide preliminary information on treatment efficacy and to supplement information on safety obtained from phase I trials. Usually, but not always, designed to include a control treatment and random allocation of patients to treatment.

PHASE II/III

A special classification arising from the AIDS context where greater testing of efficacy occurs earlier.

PHASE III TRIAL

The third and usually final stage in testing a new drug in humans. Performed as part of an approved Investigational New Drug Application under Food and Drug Administration guidelines. Concerned primarily with assessment of dosage effects and efficacy and safety. Usually designed to include a control treatment and random allocation to treatment. Once this phase is completed the drug manufacturers may request permission to market the drug by submission of a New Drug Application to the Food and Drug Administration, assuming the results of the phase I, II and III trials are consistent with such a request.

PHASE IV TRIAL

Generally, a randomized controlled trial that is designed to evaluate the long-term safety and efficacy of a drug for a given indication and that is done with Food and Drug Administration approval. Usually carried out after licensure of the drug for that indication.

PLACEBO

A pharmacologically inactive agent given to a patient as a substitute for an active agent and where the patient is not informed whether he is receiving the active or inactive agent.

PLACEBO EFFECT

The effect produced by a placebo due to the expectations of the patient. The effect in placebo-controlled clinical trials is generally measured by comparison of the effect observed in patients receiving the placebo treatment with the effect observed in patients receiving the active treatment.

PROTOCOL MONITOR

The staff person at the CPCRA Statistical Center who is primary clinic contact, and who coordinates the flow of data between the sites and the statistical center.

RANDOMIZATION

1. The process of assigning patients to treatment using a random process, such as via use of a table of random numbers. 2. The process of deriving an order or sequence of items, determinations, specimens, readings, or the like using a random process.

RANDOMIZED CONTROLLED CLINICAL TRIAL

A clinical trial that involves at least one test treatment and one control treatment, concurrent enrollment and follow-up of the test- and control-treated groups, and in which the treatments to be administered are selected by a random process, such that neither the patients nor the persons responsible for their selection or treatment can influence the assignments, and where the assignments remain unknown to the patients and clinic staff until the patients have been determined to be eligible for enrollment into the trial (and then in blinded trials may be revealed to patients and clinic personnel only by letter or number codes).

SAMPLE SIZE

The number of patients required for a trial. In planning an interventional trial, a sample size is calculated, taking into account the frequency of the condition to be prevented or delayed, the anticipated effectiveness of the treatment thought to be clinically significant, and variables such as predicted drop outs and cross overs. The sample size is a calculated value that takes all of the above into account, and makes a statistically significant result likely within the prescribed amount of time.

TREATMENT

1. The act of treating, as in caring for a patient. 2. The specific regimen, method, or procedure being tested in a clinical trial.

TREATMENT ARM

Term sometimes used in place of study treatment, or study group, especially in AIDS and cancer trials.

UNBLIND

To reveal the treatment assignment of an individual patient or group of patients to an individual or group of individuals associated with the trial (e.g., patients, study physicians, treatment effects monitoring committee) who have heretofore been denied this information.

Clinical Trial - A carefully designed investigation of the effects of a drug, medical treatment, or device on a group of subjects.

Coordinator - This individual manages the conduct of the clinical trial.

Food and Drug Administration (FDA) - A government agency that enforces laws on the manufacture, testing, and use of drugs and medical devices. All drugs and medical devices must be approved by the FDA before they can be used by the general public.

Informed consent - The legal agreement between the principal investigator and the study participant (or an authorized representative) which describes the subject's role in a clinical trial; consent must be obtained without coercion or undue influence PRIOR to participating in the clinical trial.

Institutional Review Board (IRB) - A board consisting of health care professionals from the institution where the clinical trial takes place, as well as members of the local community with the authority to approve, disapprove, or require modifications to the clinical trial. The IRB is guided by the ethical principles and regulations regarding all research involving human subjects.

Investigational treatment - The drug or medical device that is used in a clinical trial.

Phases - Drugs and medical devices undergo and must pass three stages of testing before they can be eligible for FDA approval.

Principal investigator - A medical professional who is overseeing the treatment of subjects in the clinical trial.

Protocol - A plan that sets guidelines for a trial and usually involves several different trial locations. A protocol is usually designed by the sponsor of a clinical trial.

Sponsor - The pharmaceutical company, research institution, individual or other health organization who takes responsibility for and initiates a clinical trial.