Glossary of Clinical Trial Terms

There are a lot of words and terms about clinical research that may be new to you. This section provides definitions for words and terms you may want to know.

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Adverse Event

A negative change or medical occurrence that happens during a clinical trial or within a certain time period after the trial has ended. An adverse event may or may not be caused by the treatment being studied.

Arm assignment

The assignment of a group or subgroup of participants in a clinical trial to receive interventions, or no interventions, as specified in the study protocol.

Assessment

A procedure (e.g. a blood test, scan, etc.) used to generate data required by the trial.

Background therapy

Background therapy is the current medication that is routinely taken as a standard of care for a particular condition/disease.

Blinding

A type of clinical trial design in which one or more parties involved with the trial, such as the research team or participant, do not know which treatments have been assigned to which participants. See Double-blind and Single-blind below.

Control

The control or “standard” treatment is compared against the investigational treatment. It is there to show that an approved treatment in the trial works, and the investigational treatment is compared against it.

Clinical study

A research study conducted in human volunteers to answer specific health questions. Interventional studies determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments.

Cross-over trial

A clinical trial where groups of volunteers are administered two or more interventions in a specific order. For example, a “two-by-two” cross-over trial design is where one group receives drug A at the beginning of the trial and then receives drug B for the rest of the trial. In the second group, participants receive drug B first and then drug A. Thus, the term “cross-over” is used to describe the order in which they are assigned; for example drug

A and then drug B, or drug B and then drug A. All participants receive both drugs during the study.

Dosing discontinuation

Point/time when a patient volunteer permanently stops taking study drug for any reason. This may be at the end of the study or before the end if the patient wants to stop taking the medicine for some reason.

Double-blind

In a double-blind trial, only the study pharmacist knows what study medication a participant is receiving; the participants, doctors, nurses, and other clinical trial staff are not informed.

Early patient withdrawal (premature withdrawal)

Point/time when a patient exits from a trial prior to the planned completion of all investigational/trial drug administration and all assessments (including follow-up).

Eligibility Criteria

The requirements that people who want to participate in a clinical study must meet. Eligibility Criteria include both inclusion criteria and exclusion criteria and are defined in the protocol.

European Medicines Agency (EMA)

European Medicines Agency. An agency of the European Union that oversees the use of medicinal products.

Enrolment

The point, or time, of a volunteer’s entry into the trial, after informed consent has been obtained. The same term may also be used to define the number of participants in a clinical trial.

Epoch

The planned stage of the volunteers’ participation in the trial. Typical epochs are: determination of subject eligibility, wash-out of previous treatments (i.e., a period of time when previous treatments are stopped), exposure of subject to treatment, or the follow-up on subjects after treatment has ended.

Food and Drug Administration (FDA)

Food and Drug Administration. A government agency within the U.S. Department of Health and Human Services that oversees the Nation's public health by making sure that human and veterinary drugs, vaccines, biological products, medical devices, cosmetics, dietary supplements, the food supply, and any products that give off radiation are safe, effective, and secure.

Health Authority

A national or international health agency that has authority over and regulates a clinical study.

Indication

A disease, symptom, or particular set of circumstances that make a particular test, medication, procedure, or surgery advisable. For a treatment, an indication refers to the use of that treatment in treating a particular disease.

Informed consent

Informed consent is used by researchers to explain the clinical trial to potential volunteers. Its purpose is to protect the participant. It is used when somebody who is interested in participating first asks about the study and it continues throughout the study, until the study ends. The research team will review the details of the trial with the potential participant and will answer any questions. This information is also written in a document, known as the informed consent form, which is designed to be clear and easy to understand. If a person decides to enrol in a clinical trial, they will sign the informed consent form to acknowledge that they understand the details of the trial and consent to participating. The informed consent form is not a contract and the participant can withdraw from the trial at any time, and for any reason.

Institutional Review Board (IRB)

An IRB (also known as an independent ethics committee (IEC), ethical review board (ERB) or research ethics board (REB)) is a group of doctors, scientists, advocates, researchers, and members of the community that has been formally designated to review and monitor all research involving humans. IRBs are in place to provide ethical oversight and to minimize risk to participants.

Interventional study

Also known as a clinical trial, a type of clinical study in which participants receive one or more interventions, according to the protocol and group that they are assigned to, so that researchers can evaluate the effects of the intervention on a health condition.

Investigational drug

The drug being evaluated in the trial; this definition is synonymous with “investigational new drug” or “investigational medicinal product.”

Medication number

A unique number on the label of each investigational drug package that is used in a trial to dispense and track medication. The number is used to make sure the drug is supplied in the right quantities to different research centers.

Observational study

An observational study investigates health outcomes amongst groups of people in the course of their everyday life at home, work, or the doctor’s office, where assignment of treatments or other procedures is as part of their regular medical care (not assigned by an investigator).

Outcome measure

In clinical trials, a set measurement that is described in the protocol and is used to evaluate the effect of an intervention on participants.

Part

A subdivision of a single protocol into major building blocks. These parts often are independent of each other and have different objectives or different groups of volunteers. For example, a single-dose design and a multiple-dose design may be combined into one protocol (a protocol with two parts) or the same study design could be used with different groups of patients with different severity of a disease.

Phase

Categories, defined by the Food and Drug Administration (FDA), for describing the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants. There are four phases:

- Phase I trials test an experimental drug, vaccine or device in a small group of people to evaluate safety, identify side effects and determine safe dosages.
- Phase II trials involve larger groups of people than Phase I and they are designed to assess whether an experimental treatment is safe and whether it works. This phase can last several years.
- Phase III trials are usually large studies comparing the experimental drug or vaccine to a placebo or standard treatment, to evaluate whether the drug works and collect information to allow it to be used safely.
- Phase IV trials are performed once a drug has reached the market, to provide additional information about the best use of the drug.

Placebo

Placebos are inactive substances. In a clinical trial a placebo, made to look like the investigational treatment, is sometimes used to compare against the actual investigational treatment to evaluate effectiveness.

Principal Investigator

The person who is responsible for the scientific and technical direction of the clinical trial at a specific clinical site. In most cases the principal investigator will be a leading physician in the disease area being studied.

Protocol

A written study plan on which the clinical trial is based. A protocol describes what types of people may or may not participate in the trial; the schedule of tests, procedures, medications, and dosages to be administered; the outcome measures that will be evaluated; and the length of the study.

Randomized allocation

A strategy in which participants are randomly assigned to study arms of a clinical trial by computer.

Randomization number

A unique number assigned to each randomized patient that is used to identify individuals but maintain anonymity, corresponding to a specific study arm assignment.

Run-in period

The elapsed time before a trial starts when no investigational drug is given to trial participants. During this time patients may still receive standard treatments for their disease if these treatments are allowed within the trial period.

Serious adverse event

An adverse event that is life-threatening, requires hospitalization or extended hospital stay, results in ongoing or significant incapacity, causes congenital anomalies or birth defects, or results in death.

Sponsor

The Sponsor is the organization or person who oversees multiple sites conducting the clinical trial.

Study completed date

The date on which the last trial participant made the final visit to the study location (that is, "last subject, last visit") and the last samples were collected or last tests performed.

Subject

An individual (either a healthy volunteer or a patient volunteer) whose reactions or responses to certain interventions are evaluated during a clinical trial. May also be referred to as a trial participant.

Subject number

A unique number assigned to each participant who enrols into a clinical trial.

Variable

Information collected during a clinical trial either from direct or indirect data. For example, one variable might be “weight,” which would then be checked at specified time points throughout the trial.

Wash-out period

The period of time allowed for all of the administered drug to be eliminated from the body.

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