Glossary of common terms used in clinical trials.

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Adverse event

An unfavorable change in the health of a participant, including abnormal laboratory findings, that happens during a clinical study or within a certain amount of time after the study has ended. This change may or may not be caused by the intervention/treatment being studied.

Clinical study

A research study involving human volunteers (also called participants) that is intended to add to medical knowledge. There are two types of clinical studies: interventional studies (also called clinical trials) and observational studies.

Clinical trial

Another name for an interventional study.

Condition/disease

The disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks.

Early Phase 1 (formerly listed as Phase 0)

A phase of research used to describe exploratory trials conducted before traditional phase 1 trials to investigate how or whether a drug affects the body. They involve very limited human exposure to the drug and have no therapeutic or diagnostic goals (for example, screening studies, microdose studies).

Eligibility criteria

The key requirements that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria consist of both inclusion criteria (which are required for a person to participate in the study) and exclusion criteria (which prevent a person from participating). Types of eligibility criteria include whether a study accepts healthy volunteers, has age or age group requirements, or is limited by sex.

Enrollment

The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

Exclusion criteria

A type of eligibility criteria. These are reasons that a person is not allowed to participate in a clinical study.

Inclusion criteria

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A type of eligibility criteria. These are the reasons that a person is allowed to participate in a clinical study.

Informed consent

A process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study.

For more information, see Participating in Studies on this site.

Informed consent form (ICF)

The document used in the informed consent or process.

Investigator

A researcher involved in a clinical study. Related terms include site principal investigator, site sub-investigator, study chair, study director, and study principal investigator.

Observational study

A type of clinical study in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment.

A patient registry is a type of observational study.

Other adverse event

An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

Phase

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.

Phase 1

A phase of research to describe clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.

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Phase 2

A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). For example, participants receiving the drug may be compared to similar participants receiving a different treatment, usually an inactive substance (called a placebo) or a different drug. Safety continues to be evaluated, and short-term adverse events are studied.

Phase 3

A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.

Phase 4

A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.

Phase Not Applicable

Describes trials without FDA-defined phases, including trials of devices or behavioral interventions.

Placebo

An inactive substance or treatment that looks the same as, and is given in the same way as, an active drug or intervention/treatment being studied.

Principal investigator (PI)

The person who is responsible for the scientific and technical direction of the entire clinical study.

Protocol

The written description of a clinical study. It includes the study's objectives, design, and methods. It may also include relevant scientific background and statistical information.

Recruitment status

- **Not yet recruiting:** The study has not started recruiting participants.
- **Recruiting:** The study is currently recruiting participants.
- **Enrolling by invitation:** The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. These studies are not open to

everyone who meets the eligibility criteria but only to people in that particular population, who are specifically invited to participate.

- **Active, not recruiting:** The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled.
- **Suspended:** The study has stopped early but may start again.
- **Terminated:** The study has stopped early and will not start again. Participants are no longer being examined or treated.
- **Completed:** The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred).
- **Withdrawn:** The study stopped early, before enrolling its first participant.
- **Unknown:** A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

Responsible party

The person responsible for submitting information about a clinical study to ClinicalTrials.gov and updating that information. Usually the study sponsor or investigator.

Serious adverse event

An adverse event that results in death, is life-threatening, requires inpatient hospitalization or extends a current hospital stay, results in an ongoing or significant incapacity or interferes substantially with normal life functions, or causes a congenital anomaly or birth defect. Medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above.

Sponsor

The organization or person who initiates the study and who has authority and control over the study.

Status

Indicates the current recruitment status or the expanded access status.

Study documents

Refers to the type of documents that the study sponsor or principal investigator may add to their study record. These include a study protocol, statistical analysis plan, and informed consent form.

U.S. Agency for Healthcare Research and Quality (AHRQ)

An agency within the U.S. Department of Health and Human Services. AHRQ's mission is to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used.

U.S. Food and Drug Administration (FDA)

An agency within the U.S. Department of Health and Human Services. The FDA is responsible for protecting the public health by making sure that human and veterinary drugs, vaccines and other biological products, medical devices, the Nation's food supply, cosmetics, dietary supplements, and products that give off radiation are safe, effective, and secure.