Glossary

As you consider participating in a clinical trial, you may come across some of the following terms in your research:

Active, not recruiting: The clinical study is ongoing (that is, participants are receiving an intervention or being examined), but potential participants are not currently being recruited or enrolled.

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 time period after the study is over. This may or may not be caused by the intervention being studied.

Clinical trial (or interventional study): A clinical trial is a research study in human volunteers to answer specific health questions. Carefully conducted clinical trials are the fastest and safest way that may possibly help to find treatments that work in people and ways to improve health. During the clinical trial, participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Closed studies: Clinical studies that are no longer recruiting participants because they have enough participants already, because they are completed, or because they have been stopped for some reason. This also describes studies with very specific eligibility criteria that recruit participants by invitation only.

Condition: A disease, disorder, syndrome, illness, or injury that is being studied.

Controlled trial: A type of clinical trial in which observations made during the trial are compared to a standard (called the control). The control may be observations from a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, called a "historical control").

Data Monitoring Committee (DMC): A group of independent scientists who monitor the safety and scientific integrity of a clinical trial. The group can recommend to the study sponsor that the study be stopped if it is not effective, if it is causing harm to participants, or if it is not likely to serve its scientific purpose. Committee members are chosen based on the scientific skills and knowledge needed to monitor the particular study. Also referred to as a data safety and monitoring board (DSMB).

Eligibility criteria: The key standards that people who want to participate in a clinical study must meet or the characteristics that they must have. These include inclusion criteria (factors that allow a person to participate in a study) and exclusion criteria (factors that prevent a person from participating in a study). For example, a study might only accept participants who are above or below certain ages.

Enrolling by invitation: A clinical study that selects its participants from a population, or group of people, decided on in advance by the researchers. 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.

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

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Exclusion criteria: The factors (or reasons) that prevent a person from participating in a clinical study.

Expanded access: A process regulated by the FDA that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. For more information on expanded access programs, please visit the FDA website.

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.

Health authority: A national or international health organization that has authority over the clinical study.

Human subjects review board (or Institutional Review Board (IRB)): A group of people who review, approve and monitor the clinical study protocol. Their role is to protect the rights and welfare of human research subjects participating in a study. The group typically includes people with varying backgrounds, including a community member, to make sure that research activities conducted by an organization are completely and adequately reviewed.

Inclusion criteria: The factors (or reasons) that allow a person to participate in a clinical study.

Informed consent: A process in which researchers communicate with potential and enrolled participants about a clinical study. It provides the potential benefits as well as the risks to the patient. It informs the patients that participation in the trial is voluntary, and they may discontinue participation at any time. The goal of the informed consent process is to protect participants. It begins when a potential participant first asks for information about a study and continues until the study ends.

Intervention: A process or action that is the focus of a clinical study. This can include giving participants drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches such as surveys, education, and interviews.

Investigational new drug: A drug or biological product that is used in a clinical trial but has not been approved by the FDA (the drug is either not available for a doctor to prescribe or, is available, but not approved by the FDA for the use being studied).

Investigator: A researcher involved in a clinical study.

Not yet recruiting: The clinical study has not started recruiting participants.

Open studies: Studies that are currently recruiting participants, will be recruiting participants in the future, or involve drugs that are available for expanded access.

Placebo: A substance that does not contain active ingredients and is made to be physically indistinguishable (that is, it looks and tastes identical) from the actual drug being studied.

Principal investigator (PI): The person who is responsible for the scientific and technical direction of the entire clinical study (for example, for all sites of a multisite study).

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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.

Results database: A structured online system, such as the ClinicalTrials.gov results database, that provides the public with access to summary results and registration information for completed or terminated clinical studies.

Terminated: The clinical study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated.

Withdrawn: The clinical study stopped before enrolling its first participant.