

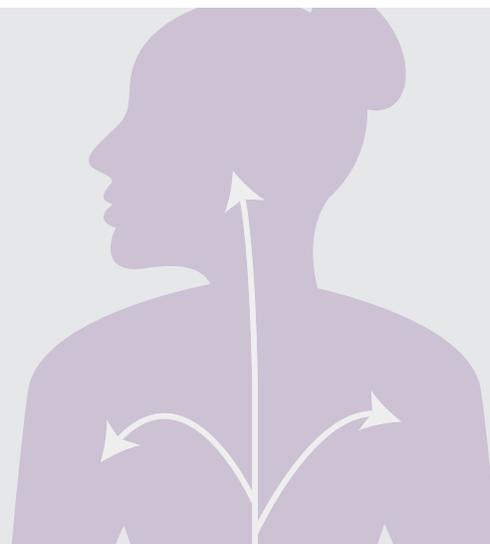
Clinical Trials Glossary of Commonly Used Terms



Foundation
for Women's Cancer



Society of Gynecologic Oncology



Administration

In medicine, the act of giving a treatment, such as a drug, to a patient. It can also refer to the way it is given, the dose, or how often it is given.

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 has ended. This change may or may not be caused by the intervention being studied.

Arm

A group or subgroup of participants in a clinical trial that receives specific interventions, or no intervention, according to the study protocol. This is decided before the trial begins.

BRCA1

A gene on chromosome 17 that normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a *BRCA1* gene has a higher risk of getting breast, ovarian, prostate, and other types of cancer.

BRCA2

A gene on chromosome 13 that normally helps to suppress cell growth. A person who inherits certain mutations (changes) in a *BRCA2* gene has a higher risk of getting breast, ovarian, prostate, and other types of cancer.

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 of a group of participants in the same trial or observations from outside the trial (for example, from an earlier trial, which is called a historical control).

Cross-over design

Describes a clinical trial in which groups of participants receive two or more interventions in a particular order. For example, a two-by-two cross-over design involves two groups of participants. One group receives drug A during the initial phase of the trial, followed by drug B during a later phase. The other group receives drug B during the initial phase, followed by drug A. So during the trial, participants “cross over” to the other drug. All participants receive drug A and drug B at some point during the trial but in a different order, depending on the group to which they are assigned.

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, is harming participants, or is unlikely to serve its scientific purpose. Members are chosen based on the scientific skills and knowledge needed to monitor the particular trial. Also referred to as a data safety and monitoring board (DSMB).

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.

Efficacy

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

The key standards that people who want to participate in a clinical study must meet or the characteristics they must have. Eligibility criteria include both inclusion criteria and exclusion criteria. For example, a study might only accept participants who are above or below certain ages.

Enrollment

The number of participants in a clinical study.

Exclusion and 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.

Health Insurance Portability and Accountability Act of 1996 (HIPAA)

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.

Genomics

The study of the complete set of DNA (including all of its genes) in a person or other organism. Almost every cell in a person's body contains a complete copy of the genome. The genome contains all the information needed for a person to develop and grow. Studying the genome may help researchers understand how genes interact with each other and with the environment and how certain diseases, such as cancer, diabetes, and heart disease, form. This may lead to new ways to diagnose, treat, and prevent disease.

Grade

In cancer, a description of a tumor based on how abnormal the cancer cells and tissue look under a microscope and how quickly the cancer cells are likely to grow and spread. Low-grade cancer cells look more like normal cells and tend to grow and spread more slowly than high-grade cancer cells. Grading systems are different for each type of cancer. They are used to help plan treatment and determine prognosis. Also called histologic grade and tumor grade.

Histology

The study of tissues and cells under a microscope.

Immunotherapy

The prevention or treatment of disease with substances that stimulate the immune response.

Informed consent

A process used by researchers to communicate with potential and enrolled participants about a clinical study. As part of the informed consent process, researchers:

- Provide all the important information about the study, so potential participants can decide whether to enroll or, if they are already enrolled, whether to continue to participate;
- Make sure that potential participants understand the risks and potential benefits of participating in the study and the alternatives to the research being conducted; and
- Stress that enrolling in, and staying in, a clinical study is completely voluntary. Because giving consent to participate in research is not a contract, participants may leave a study 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 throughout the study until the study ends. The researcher and potential participant have discussions that include answering the participant's questions about the research. All the important information about the study must also be given to the potential participant in a written document that is clear and easy to understand. The informed consent document is reviewed and approved by the human subjects review board before the document is given to potential participants. Generally, a person must sign an informed consent document to enroll in a clinical study.

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

A process or action that is the focus of a clinical study. Interventions include 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.

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.

Measurable disease

A tumor that can be accurately measured in size. This information can be used to judge response to treatment.

Neutropenia

Low neutrophils (a type of white blood cell that typically fights bacterial infections).

Overall survival

The duration of time that a study subject lives (even if their death is from non-cancer causes).

Performance status

Performance status is a score that estimates the patient's ability to perform certain activities of daily living (ADLs) without the help of others. These ADLs include basic activities such as getting dressed, eating, and bathing, as well as more complex activities such as cleaning the house and working a regular job.

Phase

Food and Drug Administration (FDA) descriptions of the clinical trial of a drug based on the study's characteristics, such as the objective and number of participants. There are five phases:

- **Early Phase 1** (Formerly listed as "Phase 0"): Exploratory study involving very limited human exposure to the drug, with no therapeutic or diagnostic goals (for example, screening studies, microdose studies).
- **Phase 1:** Studies that are usually conducted with healthy volunteers and that emphasize safety. The goal is to find out what the drug's most frequent and serious adverse events are and, often, how the drug is metabolized and excreted.
- **Phase 2:** Studies that gather preliminary data on effectiveness (whether the drug works in people who have a certain disease or condition). 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:** Studies that gather more information about safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs.
- **Phase 4:** Studies occurring after FDA has approved a drug for marketing. These include postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These studies gather additional information about a drug's safety, efficacy, or optimal use.

Placebo

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.

Platinum-refractory

The subject's disease progressed (i.e., grew) while they were receiving platinum-based chemotherapy.

Platinum-resistant

The subject had a disease-free interval of less than 6 months from the last time they received a platinum-based chemotherapy.

Platinum-sensitive

In general, this means that the subject had a disease-free interval of at least 6 months from the last time they received a platinum-based chemotherapy (most commonly carboplatin).

Primary outcome

The main question the study was designed to answer. For most drug trials, this question will be related to survival.

Progression-free survival

The duration of time that a study subject is free of disease.

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.

Randomization

Randomization is the process by which two or more alternative treatments are assigned to volunteers by chance rather than by choice.

Receptor

A molecule inside or on the surface of a cell that binds to a specific substance and causes a specific effect in the cell.

Regimen

A treatment plan that specifies the dosage, the schedule, and the duration of treatment.

Response Evaluation Criteria In Solid Tumors (RECIST)

RECIST is a set of published rules that define when tumors in cancer patients improve (respond), stay the same (stabilize), or worsen (progress) during treatment. Many clinical trials will require patients to have "measurable disease." Typically, this means that there is tumor that can be seen on an imaging study, like a CT scan, and measured to evaluate the efficacy of the study intervention.

Stage

The extent of a cancer in the body. Staging is usually based on the size of the tumor, whether lymph nodes contain cancer, and whether the cancer has spread from the original site to other parts of the body.

Thrombocytopenia

Low platelets (platelets are responsible for clotting blood).

foundationforwomenscancer.org

sgo.org

Resources

ClinicalTrials.gov Glossary of Common Site Terms

Grading and Staging of Cancer, Northwestern Medicine

National Cancer Institute Dictionary of Cancer Term

National Institutes of Health Glossary of Common Terms

Performance Status in Patients with Cancer, JAMA Oncology, October 2015