

Stanford University HRPP	Glossary of Clinical Trials Terms <i>{From https://clinicaltrials.gov/ct2/about-studies/glossary}</i>	AID-20m 1/1
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ARM	A group or subgroup of participants in a clinical trial that receives specific interventions , or no intervention, according to the study protocol.
BLINDING (or MASKING)	A clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions. Types of Masking include Open Label , Single Blind Masking , and Double Blind Masking .
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).
DOUBLE-BLIND MASKING	A type of Masking in which two or more parties involved in the clinical trial do not know which participants have been assigned which interventions. Typically, the parties include the investigator and participants.
EXPANDED ACCESS	A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. One of several Study Types .
OPEN-LABEL TRIAL	Describes a clinical trial in which masking is not used. This means that all parties involved in the trial know which participants have been assigned which interventions.
OUTCOME MEASURE	A planned measurement described in the protocol that is used to determine the effect of interventions on participants in a clinical trial. For Observational studies, a measurement or observation that is used to describe patterns of diseases or traits, or associations with exposures, risk factors, or treatment.
PHASE I TRIALS	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 II TRIALS	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 III TRIALS	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 IV TRIALS	Studies occurring after FDA has approved a drug for marketing. These including 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.
RANDOMIZED ALLOCATION	A strategy in which participants are assigned to arms of a clinical trial by chance.
SINGLE-BLIND MASKING	A type of Masking in which one party involved in the clinical trial, either the investigator or participants, does not know which participants have been assigned which interventions.