Glossary of Clinical Trial Terms

Adverse event	Unfavorable change in a person's health
Arm	Group of participants in a clinical trial
Baseline	Time point when an eligible clinical trial participant's health status is first measured
ClinicalTrials.Gov	U.S. government website that lists clinical trials
Concomitant medication	Medication taken in addition to the intervention/treatment given in a clinical trial
Control group	Clinical trial participants receiving a standard treatment or placebo rather than the potential treatment being studied
Controlled clinical trial	Clinical trial that includes a control group
Data monitoring committee (DMC)	Independent group that monitors the safety and scientific integrity of a clinical trial
Double-blind trial	Clinical trial where participants and the trial team don't know which intervention/treatment is randomly assigned to each participant
Efficacy	Ability of a potential treatment to produce a desired effect
Eligibility criteria	Requirements that clinical trial participants must meet (inclusion criteria) or not meet (exclusion criteria)
Exclusion criteria	Eligibility criteria that state the characteristics a clinical trial participant **must not have**
Good Clinical Practice (GCP)	Set of guidelines for designing and running a clinical trial to make sure results are helpful and participants are protected
Healthy volunteer	Person in a clinical trial who does not have known health problems

Inclusion criteria	Eligibility criteria that state the characteristics a clinical trial participant **must have**
Informed consent	Process followed by a clinical trial team to make sure potential participants know what will happen if they join a trial
Informed consent form	Document that provides details about a clinical trial, such as its purpose, length, procedures, risks, and potential benefits
Inpatient	Person who receives treatment and stays in a medical facility overnight
Institutional review board (IRB)/independent ethics committee (IEC)	Independent group that ensures the rights, safety, and well-being of clinical trial participants are protected
Intervention/treatment	Drug, medical device, procedure, vaccine, or change in behavior tested in a clinical trial
Investigational drug	Drug being studied to see if a person's health improves while taking it
Investigator	Researcher or healthcare provider who works on a clinical trial
Office for Human Research Protection (OHRP)	U.S. government agency whose role is to protect people in government-funded clinical trials
Open-label trial	Clinical trial where the trial team and participants know which intervention/treatment is given
Outpatient	Person who receives treatment but does not stay in a medical facility overnight
Patient volunteer	Person in a clinical trial who has a known health problem

Pharmacokinetics	Study of how the body processes a drug
Phase	Stage of a clinical trial
Placebo	Treatment or procedure that does not have any true physical effects
Pre-clinical data	Data from tests done in a laboratory before testing can be done in people
Principal investigator	Researcher or healthcare provider who leads a clinical trial
Protocol	Written plan that describes all parts of a clinical trial
Randomization	Process of assigning participants to clinical trial groups by chance
Screening	Process that determines if a person is eligible to participate in a clinical trial
Sponsor	Company, organization, or person that initiates and controls a clinical trial
Standard treatment	Most commonly used and best available treatment for a disease or health condition
Stopping rules	Safety criteria that would either pause or stop a clinical trial
Study coordinator	Person who handles day-to-day responsibilities of a clinical trial for a trial site
Study design	Plan for conducting a clinical trial