Guidance - Glossary of Clinical Trials Terms

ARM	Any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more.
BLIND	A clinical trial is "Blind" if participants are unaware of whether they are in the experimental or control arm of the study; also called masked.
CONTROLLED TRIALS	In clinical trials, one group is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.
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 therapy.
EFFICACY	(Of a drug/treatment) Maximum ability of a drug/ treatment to produce a result regardless of dosage.
ENDPOINT	Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.
EXPANDED ACCESS	Any of the FDA procedures, such as compassionate use, parallel track, and treatment IND that distribute experimental drugs to participants who are failing on currently available treatments for their condition and also are unable to participate in ongoing clinical trials.
OFF-LABEL USE	A drug prescribed for conditions other than those approved by the FDA.
OPEN-LABEL TRIAL	A clinical trial in which doctors & participants know which drug or vaccine is being administered.
PHASE I TRIALS	Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.
PHASE II TRIALS	Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.
PHASE III TRIALS	Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.
PHASE IV TRIALS	Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.
RANDOMIZED TRIAL	A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilized.
SINGLE-BLIND STUDY	A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking; also called single-masked study.
STANDARD TREATMENT	A treatment currently in wide use and approved by the FDA, considered to be effective in the treatment of a specific disease or condition.
STANDARD OF CARE	Treatment regimen or medical management based on state of the art participant care.

{From http://clinicaltrials.gov/ct2/info/glossary}

Commonly Used Acronyms

AAHRPP	Association for the Accreditation of Human Research Protection
AE	Adverse Event
CFR	Code of Federal Regulations
CITI	Collaborative IRB Training Initiative
COI	Conflict of Interest
DHHS	Department of Health and Human Services (or HHS)
DSMB/C	Data Safety Monitoring Board/Committee
FDA	Food and Drug Administration
FWA	Federalwide Assurance
HIPAA	Health Insurance Portability and Accountability Act (1996)
HRPP	Human Research Protection Program
HSR	Human Subjects Research
IDE	Investigational Device Exemption
IND	Investigational New Drug
IRB	Institutional Review Board
LAR	Legally Authorized Representative
MTA	Material Transfer Agreement
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
PI	Principal Investigator
PHI	Protected Health Information
PHS	Public Health System
PRIM&R	Public Responsibility in Medicine and Research
ORC	Office of Research Compliance
OSP	Office of Sponsored Research
SAE	Serious Adverse Event
SIR	Sponsor Investigator Research
UP	Unanticipated Problem (Involving Risks to Participants or Others)