Glossary of Common Site Terms

This glossary will help you understand words and phrases frequently used on ClinicalTrials.gov. Many of these words are also used by clinical researchers and others in the same or a similar manner. But the definitions below are provided to explain content on ClinicalTrials.gov only.

For help with medical terms, see the MeSH (Medical Subject Headings) Dictionary.

Study record managers should refer to the Protocol Registration Data Element Definitions, Expanded Access Data Element Definitions, and Results Data Element Definitions for help with the data items required to register a study and submit results using the ClinicalTrials.gov Protocol Registration and Results System.

ACCEPTS HEALTHY VOLUNTEERS
Indicates whether a clinical study allows people who do not have the condition or related conditions or symptoms being studied to participate in that study. (See also Accepts Healthy Volunteers data element on ClinicalTrials.gov.)

ACTIVE COMPARATOR ARM
A group of participants that receives an intervention that is considered to be effective. One of several Arm Types.

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. A type of Recruitment Status.

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. (See also Adverse Events results data element on ClinicalTrials.gov.)

ALLOCATION
A clinical trial design strategy used to assign participants to an arm of a study. Types of Allocations include randomized and nonrandomized. (See also Allocation data element on ClinicalTrials.gov.)

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.

ARM TYPE
A general description of the clinical study arm. It identifies the role of the intervention that participants will receive. Types of arms include Experimental, Active Comparator, Placebo Comparator, Sham Comparator, and No Intervention. (See also Arm Type data element on ClinicalTrials.gov.)

BASELINE CHARACTERISTICS
Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and gender, and study-specific measures (for example, systolic blood pressure, prior antidepressant treatment). (See also Baseline Characteristics results data element on ClinicalTrials.gov.)

BLINDING (or Masking)
See Masking (or Blinding).
CERTAIN AGREEMENTS
As required by Section 801 of the Food and Drug Administration Amendments Act, in general, a description of any agreement between the Sponsor of a clinical study and the Principal Investigator (PI) that does not allow the PI to discuss the results of the study or publish the study results in a scientific or academic journal after the trial is completed. (This does not apply if the PI is an employee of the Sponsor.) (See also Certain Agreements results data element on ClinicalTrials.gov)

CLINICAL STUDY
A research study using human subjects to evaluate biomedical or health-related outcomes. Two types of clinical studies are Interventional studies (or clinical trials) and Observational studies.

CLINICAL TRIAL (or Interventional Study)
See Interventional Study.

CLINICALTRIALS.GOV IDENTIFIER (NCT NUMBER)
A unique identification code is given to each clinical study registered on ClinicalTrials.gov. Because the format is "NCT" followed by an 8-digit number (for example, NCT00000419), this identifier is also known as the NCT Number.

CLOSED STUDIES
Clinical studies that are no longer recruiting participants because they have enough participants already, have ended, or have been stopped for some reason. This term also describes studies with very specific Eligibility Criteria that recruit participants by invitation only. Recruitment statuses for closed studies appear in red text in ClinicalTrials.gov search results and study records. These statuses are:

Active, not recruiting
Completed
Terminated
Suspected
Withdrawn
Enrolling by invitation
Temporarily not available for expanded access
No longer available for expanded access
Approved for marketing
Unknown

Note: The word "Unknown" in brown text means that a study record has passed its completion date and the recruiting status has not been verified on ClinicalTrials.gov within the past 2 years. (See also Last Verified Date.)

COLLABORATOR
A Collaborator is an organization other than the Sponsor that provides support for a clinical study. This support may include funding, design, implementation, data analysis, or reporting. (See also Collaborators data element on ClinicalTrials.gov)

COMPLETED
The clinical study has ended normally, and participants are no longer being examined or treated (that is, the "last subject, last visit" has occurred). A type of Recruitment Status.

CONDITION
The disease, disorder, syndrome, illness, or injury that is being studied. On ClinicalTrials.gov, conditions may also include other health-related issues, such as lifespan, quality of life, and health risks. (See also Conditions or Focus of Study data element on ClinicalTrials.gov)

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. One type of Intervention Model (design).
D

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). (See also Data Monitoring Committee data element on ClinicalTrials.gov.)

DMC
See Data Monitoring Committee (DMC).

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.

E

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. (See also Eligibility Criteria data element on ClinicalTrials.gov.)

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. A type of Recruitment Status.

ENROLLMENT
The number of participants in a clinical study. The "estimated enrollment" is the number of participants that the researchers need for the study. (See also Enrollment data element on ClinicalTrials.gov.)

EXCLUSION CRITERIA
The factors, or reasons, that prevent a person from participating in a clinical study.

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.

For more information on expanded access, visit the Expanded Access: Information for Patients page on the FDA Web site.

EXPERIMENTAL ARM
A group of participants that receives the intervention that is the focus of the study. One of several Arm Types.

F

FACTORIAL DESIGN
Describes a clinical study in which groups of participants receive one of several combinations of interventions. For example, a two-by-two factorial design involves four groups of participants. Each group receives one of the following pairs of interventions: 1) drug A and drug B, 2) drug A and a placebo, 3) a placebo and drug B, or 4) a placebo and a placebo. So during the trial, all possible combinations of the two drugs (A and B) and the placebos are given to different groups of participants. One type of Intervention Model (design).

FDA
Food and Drug Administration. See also Food and Drug Administration (FDA).

FDAA 801
Section 801 of the Food and Drug Administration Amendments Act of 2007 (U.S. Public Law 110-85). See also Section 801 of the Food and Drug Administration Amendments Act (FDAA 801).

FIRST RECEIVED DATE
The First Received date is the date on which summary clinical study protocol information was first submitted to the ClinicalTrials.gov registry. There is typically a delay of a few days between the First Received date and when the study information is available on ClinicalTrials.gov.

FOOD AND DRUG ADMINISTRATION (FDA)
An agency within the U.S. Department of Health and Human Services, 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.

FUNDER TYPE
Describes the organization that provides funding or support for a clinical study. Support may include providing facilities, expertise, or financial resources. Organizations listed as Sponsors and Collaborators for a study are considered the funders of the study. There are four types of funders:
- National Institutes of Health
- Other U.S. Federal agencies (for example, the Food and Drug Administration, Centers for Disease Control and Prevention, U.S. Department of Veterans Affairs)
- Industry (pharmaceutical and device companies)
- All others (including individuals, universities, and community-based organizations)

G

GENDERS ELIGIBLE FOR STUDY
The physical gender of people who may participate in a clinical study (Female, Male, or Both). (See also Gender data element on ClinicalTrials.gov.)

H

HAS DATA MONITORING COMMITTEE (DMC)
Indicates whether the clinical trial has a data monitoring committee (DMC) or a data safety and monitoring board (DSMB). (See also Data Monitoring Committee data element on ClinicalTrials.gov.)

HAS RESULTS
Indicates that summary information about the results of a clinical study registered on ClinicalTrials.gov, is available in the ClinicalTrials.gov results database and can be viewed in the study record.

HEALTH AUTHORITY
A national or international health organization that has authority over a clinical study. (See also Oversight Authorities data element on ClinicalTrials.gov.)

HUMAN SUBJECTS REVIEW BOARD
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. Also known as an institutional review board (IRB) or ethics committee. (See also Human Subjects Review data element on ClinicalTrials.gov.)

I

INCLUSION CRITERIA
The factors, or reasons, that allow a person to participate in a clinical study.

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.
- 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.

**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.

**INTERVENTION MODEL (Design)**

The general design of the strategy for assigning interventions to participants in a clinical study. Types of Intervention Models include Single Group design, Parallel design, Cross-over design, and Factorial design. (See also Intervention Model data element on ClinicalTrials.gov.)

**INTERVENTION NAME**

The intervention being studied. (See also Intervention Name data element on ClinicalTrials.gov.)

**INTERVENTION TYPE**

The general category of the intervention being studied. Intervention Types include Drug, Device, Biological/Vaccine, and Procedure/Surgery, among others. (See also Intervention Type data element on ClinicalTrials.gov.)

**INTERVENTIONAL STUDY (or Clinical Trial)**

A clinical study in which 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. A Study Type.

**INVESTIGATIONAL NEW DRUG**

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

**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. (See also Investigators data element on ClinicalTrials.gov.)

**LAST UPDATED DATE**

The Last Updated date is the most recent date on which changes to a study record were submitted to ClinicalTrials.gov. There may be a delay between the Last Updated date and when the updated study information is available on ClinicalTrials.gov. Also, this date may be different from the Last Verified date.

**LAST VERIFIED DATE**

The Last Verified date is the most recent date on which all of a clinical study’s information on ClinicalTrials.gov was confirmed as accurate and current. This date may be different from the Last Updated date. If a study with a status of Recruiting; Not yet recruiting; or Active, not recruiting has not been confirmed within the past 2 years, the study’s Recruitment status is shown as Unknown. (See also Record Verification Date data element on ClinicalTrials.gov.)

**LISTED LOCATION COUNTRIES**
Countries in which research facilities for a study are located. A country is listed only once, even if there is more than one facility in the country. The list includes all countries as of the Last Updated date; any country for which all facilities were removed from the study record are listed under Removed Location Countries. (See also Facility Contact data element on ClinicalTrials.gov.)

M

MASKING (or Blinding)
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.

N

NCT NUMBER (or ClinicalTrials.gov Identifier)
See ClinicalTrials.gov Identifier (NCT Number).

NO INTERVENTION ARM
A group of participants that does not receive any interventions during a clinical study. One of several Arm Types.

NOT YET RECRUITING
The clinical study has not started recruiting participants. A type of Recruitment Status.

O

OBSERVATIONAL STUDY
A clinical study in which participants identified as belonging to study groups are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to specific interventions (as in an Interventional study). A Study Type.

OBSERVATIONAL STUDY MODEL (Design)
The general design of the strategy for identifying and following up with participants during Observational studies. Types of Observational Study Models include Cohort, Case-control, Case-only, Case-cross-over, Ecologic or community studies, Family-based, and Other. (See also Observational Study Model data element on ClinicalTrials.gov.)

OPEN LABEL
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.

OPEN STUDIES
Clinical studies that are currently recruiting participants, will be recruiting participants in the future, or involve drugs that are available for expanded access. Recruitment statuses for open studies appear in green text in ClinicalTrials.gov search results and study records. These statuses are:
- Recruiting
- Not yet recruiting
- Available for expanded access

OTHER ADVERSE EVENT
An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above. (See also Adverse Events results data element on ClinicalTrials.gov.)
OTHER IDS
See Other Study ID Numbers.

OTHER STUDY ID NUMBERS
Identification numbers assigned to the clinical study protocol by the study sponsor, funders, or others. These numbers include unique identifiers from other registries and National Institutes of Health grant numbers. (See also Secondary IDs data element on ClinicalTrials.gov.)

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. Types of Outcome Measures include Primary Outcome Measure and Secondary Outcome Measure. (See also Primary and Secondary Outcome Measures data element and Outcome Measure results data element on ClinicalTrials.gov.)

PARALLEL DESIGN
Describes a clinical trial in which two or more groups of participants receive different interventions. For example, a two-arm parallel design involves two groups of participants. One group receives drug A, and the other group receives drug B. So during the trial, participants in one group receive drug A "in parallel" to participants in the other group, who receive drug B. One type of Intervention Model (design).

PARTICIPANT FLOW
A summary of the progress of participants through each stage of a clinical study, by study arm. This includes the number of participants who started, completed, and dropped out of the study. (See also Participant Flow results data element on ClinicalTrials.gov.)

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:

- 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 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.

(See also Study Phase data element on ClinicalTrials.gov.)

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.

PLACEBO COMPARATOR ARM
A group of participants that receives a placebo during a clinical study. One of several Arm Types.

PRIMARY COMPLETION DATE
The date on which the last participant in a clinical study was examined or received an intervention and that data for the Primary Outcome Measure were collected. Whether the clinical study ended according to the protocol or was terminated does not affect this date. The "estimated primary completion date" is the date that the researchers think will be the Primary Completion Date for the study. The Primary Completion Date is the term used on ClinicalTrials.gov for "completion date" as defined in Section 801 of the Food and Drug Administration Amendments Act of 2007. (See also Primary Completion Date data element on ClinicalTrials.gov.)

PRIMARY OUTCOME MEASURE
The planned Outcome Measure in the protocol that is the most important for evaluating the effect of an intervention. Most clinical studies have one Primary Outcome Measure, but some may have more than one. (See also Primary Outcome Measure data element on ClinicalTrials.gov.)

PRIMARY PURPOSE
The main reason for the clinical trial. The types of Primary Purposes are Treatment, Prevention, Diagnostic, Supportive Care, Screening, Health Services Research, Basic Science, and Other. (See also Primary Purpose data element on ClinicalTrials.gov.)

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).

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.

PUBLICATIONS
Published scientific articles or abstracts about a clinical study. A publication reference, also called a citation, may be submitted to ClinicalTrials.gov at any time. It can also be automatically identified by the ClinicalTrials.gov Identifier (NCT Number), which is indexed in MEDLINE®, a database of biomedical and life sciences journal citations.

R
RANDOMIZED ALLOCATION
A strategy in which participants are assigned to arms of a clinical trial by chance. A type of Allocation.

RANK
Indicates the order in which studies appear on the Search Results list. The studies most relevant to the search terms appear higher on the list.

RECORD
See Study Record.

RECRUITING
The clinical study is currently recruiting participants. A type of Recruitment Status.

RECRUITMENT STATUS
Indicates the current stage of a clinical study and whether it is or will be open for enrollment. The possible Recruitment Statuses are:

<table>
<thead>
<tr>
<th>Open Studies</th>
<th>Closed Studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruiting</td>
<td>Active, not recruiting</td>
</tr>
<tr>
<td>Not yet recruiting</td>
<td>Completed</td>
</tr>
<tr>
<td>Available for expanded access</td>
<td>Terminated</td>
</tr>
<tr>
<td>Recruiting</td>
<td>Suspended</td>
</tr>
<tr>
<td>Not yet recruiting</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>Recruiting</td>
<td>Enrolling by invitation</td>
</tr>
</tbody>
</table>

- Recruiting: The study is currently recruiting participants.
- Not yet recruiting: The study has not started recruiting participants.
- Available for expanded access: Expanded access is currently available for this study intervention.
- Active, not recruiting: The study is ongoing (that is, participants are receiving an intervention or being examined), but potential participants are not currently being recruited or enrolled.
- Completed: The study has ended normally, and participants are no longer being examined or treated (that is, the "last subject, last visit" has occurred).
- Terminated: The study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated.
- Suspended: The study has stopped recruiting or enrolling participants early but may start again.
- Withdrawn: The study stopped early, before enrolling its first participant.
- Enrolling by invitation: A 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.

| Temporarily not available for expanded access | Expanded access is not currently available for this intervention but is expected to be available in the future. |
| No longer available for expanded access | Expanded access was available for this intervention previously but is not currently available and will not be available in the future. |
| Approved for marketing | Applies to expanded access. The intervention has been approved by the Food and Drug Administration for use by the public. |
| Unknown | A study in ClinicalTrials.gov whose last known status was Recruiting; Not yet recruiting, or Active, not recruiting but the study has passed its completion date and the status has not been verified within the past 2 years. |

(See also Overall Recruitment Status data element and Recruitment Status data element on ClinicalTrials.gov.)

REGISTRATION
The process of submitting and updating summary information about a clinical study protocol, from its beginning to end, to a structured, Web-based registry that is accessible to the public, such as ClinicalTrials.gov.

REGISTRY
A structured online system, such as ClinicalTrials.gov, that provides the public with access to summary information about ongoing and completed clinical studies.

REMOVED LOCATION COUNTRIES
Countries that appeared under Listed Location Countries but were removed from the study record by the data provider.

REPORTING (OR COMPARISON) GROUP
A grouping of participants in a clinical study that is used in summarizing the data collected during the study. This grouping may be the same as or different from a study arm.

RESPONSIBLE PARTY
The Sponsor, Sponsor-Investigator, or Sponsor-designated Principal Investigator who is responsible for submitting information about a clinical study to ClinicalTrials.gov and updating that information. (See also Responsible Party data element on ClinicalTrials.gov.)

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

Note: The ClinicalTrials.gov results database became available in September 2008. Older studies are unlikely to have results available in the database.

RESULTS FIRST RECEIVED DATE
The date on which summary information about the results of a clinical study was first submitted to the ClinicalTrials.gov results database.

RESULTS SUBMISSION
The process of submitting and updating summary information about the results of a clinical study to a structured, publicly accessible, Web-based results database, such as the ClinicalTrials.gov results database.

SECONDARY OUTCOME MEASURE
A planned Outcome Measure in the protocol that is not as important as the Primary Outcome Measure but is still of interest in evaluating the effect of an intervention. Most clinical studies have more than one Secondary Outcome Measure. (See also Secondary Outcome Measures data element on ClinicalTrials.gov.)

SECTION 801 OF THE FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT (FDAAA 801)
Section 801 of U.S. Public Law 110-85, which was enacted on September 27, 2007. It amends Section 402 of the U.S. Public Health Service Act to expand the clinical study registry known as ClinicalTrials.gov and create a clinical study results database.
SERIOUS ADVERSE EVENT
An adverse event that results in death, is life-threatening, requires inpatient hospitalization or extends a current hospital stay, results in an ongoing or significant incapacity or interferes substantially with normal life functions, or causes a congenital anomaly or birth defect. Medical events that do not result in death, are not life-threatening, or do not require hospitalization may be considered serious adverse events if they put the participant in danger or require medical or surgical intervention to prevent one of the results listed above. (See also Adverse Events results data element on ClinicalTrials.gov.)

SHAM COMPARATOR ARM
A group of participants that receives a procedure or device that is made to be indistinguishable from the actual procedure or device being studied but does not contain active processes or components. One of several Arm Types.

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.

SINGLE GROUP DESIGN
Describes a clinical trial in which all participants receive the same intervention. One type of Intervention Model/design.

SPONSOR (LEAD)
The Sponsor is the organization or person (see also Sponsor-Investigator) who oversees the clinical study and is responsible for analyzing the study data. (See also Sponsor data element on ClinicalTrials.gov.)

SPONSOR-INVESTIGATOR
The person who both initiates and conducts the clinical study.

STATUS
See Recruitment Status.

STUDY COMPLETION DATE
The date on which the final data for a clinical study were collected because the last study participant made the final visit to the study location (that is, "last subject, last visit"). The "estimated study completion date" is the date that the researchers think will be the completion date for the study. (See also Study Completion Date data element on ClinicalTrials.gov.)

STUDY DESIGN
The investigative methods used in the clinical study. For Interventional studies, these include Primary Purpose, Intervention Model/design, Masking (or blinding), and Allocation. (See also Study Design data element on ClinicalTrials.gov.)

STUDY RECORD
An entry on ClinicalTrials.gov that contains summary protocol information about a clinical study, such as Recruitment Status, Eligibility Criteria, contact information; and, in some cases, summary results. Each study record is assigned a ClinicalTrials.gov Identifier (NCT Number).

STUDY START DATE
The date on which the enrollment of participants for a clinical study began. (See also Study Start Date data element on ClinicalTrials.gov.)

STUDY TYPE
Describes the nature of a clinical study. Study Types include Interventional studies (or clinical trials), Observational studies, and Expanded Access. (See also Study Type data element on ClinicalTrials.gov.)

SUSPENDED
The clinical study has stopped recruiting or enrolling participants early, but it may start again. A type of Recruitment Status.

T

TERMINATED
The clinical study has stopped recruiting or enrolling participants early and will not start again. Participants are no longer being examined or treated. A type of Recruitment Status.

TIME FRAME, OUTCOME MEASURE
The points in time at which an Outcome Measure is assessed. These times are planned before the clinical study starts and are listed in the protocol. (See also Primary and Secondary Outcome Measures data element and Outcome Measure Time Frame results data element on ClinicalTrials.gov.)

**TITLE ACRONYM**

The acronym or initials used to identify a clinical study, if provided. For example, the title acronym for the Women's Health Initiative is "WHI." (See also Acronym data element on ClinicalTrials.gov.)

**UNKNOWN (RECRUITMENT STATUS)**

A study in ClinicalTrials.gov whose last known status was Recruiting; Not yet recruiting; or Active, not recruiting but the study has passed its completion date and the status has not been verified within the past 2 years. Studies with an Unknown status are considered closed studies.

**VERIFICATION DATE**

See Last Verified Date.

**WITHDRAWN**

The clinical study stopped before enrolling its first participant. A type of Recruitment Status.

This page last reviewed in January 2017