Definitions were obtained from https://www.clinicaltrials.gov/study-basics/glossary

Clinical Trial

1. Study Information:

**NCT Number**

The unique identification code given to each clinical study upon registration at ClinicalTrials.gov. The format is "NCT" followed by an 8-digit number (for example, NCT00000419).

**Study Title**

The official title of a protocol used to identify a clinical study or a short title written in language intended for the lay public.

**Study URL**

The link to the official page of the study

**Acronym**

The acronym or initials used to identify a clinical study (not all studies have one). For example, the title acronym for the Women's Health Initiative is "WHI."

**Study Status**

Recruitment status

Not yet recruiting: The study has not started recruiting participants.

Recruiting: The study is currently recruiting participants.

Enrolling by invitation: The study is selecting its participants from a population, or group of people, decided on by the researchers in advance. 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.

Active, not recruiting: The study is ongoing, and participants are receiving an intervention or being examined, but potential participants are not currently being recruited or enrolled.

Suspended: The study has stopped early but may start again.

Terminated: The study has stopped early and will not start again. Participants are no longer being examined or treated.

Completed: The study has ended normally, and participants are no longer being examined or treated (that is, the last participant's last visit has occurred).

Withdrawn: The study stopped early, before enrolling its first participant.

Unknown: A study on ClinicalTrials.gov whose last known status was recruiting; not yet recruiting; or active, not recruiting but that has passed its completion date, and the status has not been last verified within the past 2 years.

**Brief Summary**

**Study Results**

Bool to check whether there are any results

**Start Date**

The actual date on which the first participant was enrolled in a clinical study. The "estimated" study start date is the date that the researchers think will be the study start date.

**Primary Completion Date**

The date on which the last participant in a clinical study was examined or received an intervention to collect final data for the primary outcome measure. Whether the clinical study ended according to the protocol or was terminated does not affect this date. For clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all the primary outcome measures. The "estimated" primary completion date is the date that the researchers think will be the primary completion date for the study.

**Completion Date**

Actual date the study is completely done

**First Posted**

The date on which the study record was first available on ClinicalTrials.gov after National Library of Medicine (NLM) quality control (QC) review has concluded. There is typically a delay of a few days between the date the study sponsor or investigator submitted the study record and the first posted date.

**Results First Posted**

The date on which summary results information was first available on ClinicalTrials.gov after National Library of Medicine (NLM) quality control (QC) review has concluded. There is typically a delay between the date the study sponsor or investigator first submits summary results information (the results first submitted date) and the results first posted date. Some results information may be available at an earlier date if Results First Posted with QC Comments.

**Last Update Posted**

The most recent date on which changes to a study record were made available on ClinicalTrials.gov. There may be a delay between when the changes were submitted to ClinicalTrials.gov by the study's sponsor or investigator (the last update submitted date) and the last update posted date.

**Study Documents**

1. Participant Information:

**Sex**

A type of eligibility criteria that indicates the sex of people who may participate in a clinical study (all, female, male). Sex is a person's classification as female or male based on biological distinctions. Sex is distinct from gender-based eligibility.

**Age**

A type of eligibility criteria that indicates the age a person must be to participate in a clinical study. This may be indicated by a specific age or the following age groups:

The age groups are:

Child (birth-17)

Adult (18-64)

Older Adult (65+)

**Enrollment**

The number of participants in a clinical study. The "estimated" enrollment is the target number of participants that the researchers need for the study.

1. Medical Details:

**Conditions**

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

**Interventions**

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 education or modifying diet and exercise.

**Primary Outcome Measures**

In a clinical study's protocol, the planned outcome measure that is the most important for evaluating the effect of an intervention/treatment. Most clinical studies have one primary outcome measure, but some have more than one.

**Secondary Outcome Measures**

In a clinical study's protocol, a planned outcome measure that is not as important as the primary outcome measure for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.

**Other Outcome Measures**

In a clinical study's protocol, a planned outcome measure that is not as important as the primary or secondary outcome measure for evaluating the effect of an intervention but is still of interest. Most clinical studies have more than one secondary outcome measure.

**Phases**

The stage of a clinical trial studying a drug or biological product, based on definitions developed by the U.S. Food and Drug Administration (FDA). The phase is based on the study's objective, the number of participants, and other characteristics. There are five phases: Early Phase 1 (formerly listed as Phase 0), Phase 1, Phase 2, Phase 3, and Phase 4. Not Applicable is used to describe trials without FDA-defined phases, including trials of devices or behavioral interventions.

* **Phase 1:** A phase of research to describe clinical trials that focus on the safety of a drug. They are usually conducted with healthy volunteers, and the goal is to determine the drug's most frequent and serious adverse events and, often, how the drug is broken down and excreted by the body. These trials usually involve a small number of participants.
* **Phase 2:** A phase of research to describe clinical trials that gather preliminary data on whether a drug works in people who have a certain condition/disease (that is, the drug's effectiveness). 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:** A phase of research to describe clinical trials that gather more information about a drug's safety and effectiveness by studying different populations and different dosages and by using the drug in combination with other drugs. These studies typically involve more participants.
* **Phase 4:** A phase of research to describe clinical trials occurring after FDA has approved a drug for marketing. They include postmarket requirement and commitment studies that are required of or agreed to by the study sponsor. These trials gather additional information about a drug's safety, efficacy, or optimal use.
* **Phase not applicable:** Describes trials without FDA-defined phases, including trials of devices or behavioral interventions.

**Study Type**

Describes the nature of a clinical study. Study types include interventional studies (also called clinical trials), observational studies (including patient registries), and expanded access.

* **Interventional study (clinical trial):** A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (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's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.
* **Observational study:** A type of clinical study in which participants are identified as belonging to study groups and 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 a specific interventions/treatment.
* **A patient registry is a type of observational study.**
* **Expanded access:** A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use. There are different expanded access types.

**Study Design**

The investigative methods and strategies used in the clinical study.

**Other IDs**

Identifiers or ID numbers other than the NCT number that are assigned to a clinical study by the study's sponsor, funders, or others. These numbers may include unique identifiers from other trial registries and National Institutes of Health grant numbers.

1. Collaboration Details:

**Funder Type**

Describes the organization that provides funding or support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting. Organizations listed as sponsors and collaborators for a study are considered the funders of the study. ClinicalTrials.gov refers to four types of funders:

U.S. National Institutes of Health

Other U.S. Federal agencies (for example, Food and Drug Administration, Centers for Disease Control and Prevention, or U.S. Department of Veterans Affairs)

Industry (for example: pharmaceutical and device companies)

All others (including individuals, universities, and community-based organizations)

**Sponsor**

The organization or person who initiates the study and who has authority and control over the study.

**Collaborators**

An organization other than the sponsor that provides support for a clinical study. This support may include activities related to funding, design, implementation, data analysis, or reporting.

1. Location Information:

**Locations**

In the search feature, the Location terms field is used to narrow a search by location-related terms other than Country, State, and City or distance. For example, you may enter a specific facility name (such as National Institutes of Health Clinical Center) or a part of a facility name (such as Veteran for studies listing Veterans Hospital or Veteran Affairs in the facility name). Note: Not all study records include this level of detail about locations.

Definitions were obtained from https://www.clinicaltrials.gov/study-basics/glossary

Clinical Trial

1. Study Information:

**NCT Number:** string

**Study Title:** string

**Study URL:** url

**Acronym:** string

**Study Status:** string

**Brief Summary:** string

**Study Results:** bool

**Start Date:** date

**Primary Completion Date:** date

**Completion Date:** date

**First Posted:** date

**Results First Posted:** date

**Last Update Posted:** date

**Study Documents:** string +url

1. Participant Information:

**Sex:** string

**Age:** string

**Enrollment:** int

1. Medical Details:

**Conditions:** string

**Interventions:** string

**Primary Outcome Measures**: string

**Secondary Outcome Measures:** string

**Other Outcome Measures:** string

**Phases:** string

**Study Type:** string

* **Interventional study (clinical trial):** A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (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's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.
* **Observational study:** A type of clinical study in which participants are identified as belonging to study groups and 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 a specific interventions/treatment.
* **A patient registry is a type of observational study.**
* **Expanded access:** A way for patients with serious diseases or conditions who cannot participate in a clinical trial to gain access to a medical product that has not been approved by the U.S. Food and Drug Administration (FDA). Also called compassionate use. There are different expanded access types.

**Study Design:** string

**Other IDs:** string

1. Collaboration Details:

**Funder Type:** string

**Sponsor:** string

**Collaborators:** string

1. Location Information:

**Locations:** string