The Raremark Clinical Trials Glossary

Adverse event

An adverse event is any unexpected or unwanted result in someone who joins a clinical trial and takes a drug or treatment being tested. An adverse event could be a bad side effect, an unexpected *good* result from taking the drug or treatment, or a result that has nothing at all to do with the treatment itself.

Blinded study

There are two types of blinded clinical trials:
Single blind: when only the researcher (but not the participants) knows who's getting the tested drug or treatment, and who's not.
Double blind: when **neither** the researcher nor the participants knows who's getting the tested drug or treatment.

Clinical trial (clinical study)

A clinical trial tests new drugs and treatments on people, to see whether these treatments are safe and effective before they go on the market.

Control group

A control group is made up of people who don't get the drug or treatment that researchers are testing.

Efficacy

Efficacy is whether the drug or treatment that researchers are testing gives the result that they'd expect (or want) to see.

Eligibility criteria

Eligibility criteria are the requirements that people need to meet before they can take part in a clinical trial. For example, a study's eligibility criteria could include being female and over the age of 25.

Endpoint

An endpoint is what researchers measure to see whether a new drug or treatment works. An example of an endpoint is the measurement of how much pain someone still has after treatment with a new drug.

Enrollment

Enrollment is the process of registering or adding people into a clinical trial.

Ethics Review Board

An ethics review board is an independent group that protects the rights, safety and well-being of people in a clinical trial. Before a clinical trial can start, they have to approve how researchers plan to run it.

Inclusion and exclusion criteria

There are two types of eligibility criteria:
Inclusion criteria: Traits that people who want to be in a clinical trial **must** have, or they won't be allowed to join. For example, a clinical trial may only want to test a treatment on people who smoke menthol cigarettes.
Exclusion criteria: Traits that people who want to be in a clinical trial **must not** have, or they won't be allowed to join. For example, researchers may **not** want to include people who only smoke e-cigarettes.

Informed assent

Children and teenagers can take part in clinical trials. When they do so, they give what's called informed *assent*, because they aren't old enough to give fully informed *consent* (see below).
Researchers will explain what the study involves in a way that younger people can understand. Giving informed assent means the child or teenager understands what they've been told about the clinical trial, and they agree to take part.

Informed consent

Clinical trial informed consent is when doctors or researchers share information about a study with people who may want to join it. They'll learn things like: What is this research for? What treatment is being tested? What is the treatment schedule? What are the possible risks and benefits of this treatment? What are your rights when you join this study?

Informed consent is a good time for people to ask questions about the clinical trial that they want to join. Once all questions have been answered, participants must sign an informed consent form to say they understand what they'll need to do (and what may happen) during the study.

Open-label study

An open-label study is a clinical trial where the subjects **and** the researchers know who's receiving the tested drug or treatment. There are no control groups (nobody gets a placebo) in these studies.

Participant, or subject

Participants or subjects are people who are willing to join a clinical trial. Participation in clinical trials is always voluntary; no one can force you to sign up, or to stay in the study after it's started.

Phases

Phases are the different stages of a clinical trial. There are usually three stages (Phase 1, Phase 2 and Phase 3), and in some cases a fourth (Phase 4).

Placebo

A placebo looks the same as the drug being studied, but it doesn't have any active ingredients. For example, a placebo could be a sugar pill.

Principal investigator (PI)

A principal investigator is the person who leads the research team – usually a doctor or specialist in the disease.

Protocol

A protocol is a written plan for the clinical trial that explains how everything will be done.

Randomization

Randomization is when researchers put people in either the treatment group or the control group totally by chance (for example, flipping a coin could be used for randomization, or a computer program could randomly choose who goes in the different groups).

Schedule of events

Clinical trials follow procedures that are set up at regular intervals (for example, every two weeks).

Study sample

A study sample is a group of people that researchers will study during a clinical trial.

Sponsor

A trial sponsor is the organization or person paying for the research; it might be a drug company, an academic researcher, a doctor or a hospital.

Study coordinator

A study coordinator is a person who helps the principal investigator run a clinical trial on a day-to-day basis. The coordinator solves problems and makes sure the different people or organizations involved in the study get the information, supplies, and follow-up that they need.

Treatment group

A treatment group is a group of subjects that receive the drug or treatment being tested.

For further information on your condition, visit your community homepage at www.raremark.com. Sign up to our newsletter to receive the latest news and research for your rare disease.

raremark

Sources:

CDISC, 2011. CDISC Clinical Research Glossary. Available at: https://www.cdisc.org/system/files/all/standard_category/application/pdf/act1211_011_043_gr_glossary.pdf [Accessed on: 04.04.18]

Raremark, 2017. What to expect from a clinical trial. Available at: https://raremark.com/articles/what-to-expect-from-a-clinical-trial--719 [Accessed on: 04.04.18]

Raremark, 2017. Everything you should know about clinical trials. Available at: https://raremark.com/articles/clinical-trials--712 [Accessed on: 04.04.18]