Clinical Trials Glossary

Adverse event: An unexpected or unwanted result in a study participant, which may be caused by the treatment or by other factors. Adverse events can range from mild to severe and may include symptoms such as nausea, headache, or dizziness.

Blinded study: A study in which the participants, investigators, or both are not aware of who is receiving the treatment and who is receiving the placebo. This helps to reduce bias in the results.

Control group: A group of subjects that does not receive the drug or treatment being tested. This group is used as a comparison to the treatment group.

Eligibility criteria: The requirements that participants must meet in order to be included in a clinical trial. These criteria are established by the study sponsor and are based on factors such as age, gender, and health status.

Endpoint: A specific measurement or outcome that is used to evaluate the effectiveness of a treatment. Endpoints may include survival rates, symptom improvement, or other health-related metrics.

Ethics Review Board: An independent committee that reviews and approves clinical trials to ensure they are conducted ethically and with the well-being of participants in mind.

Inclusion and exclusion criteria: The criteria that determine whether a participant is eligible to join a clinical trial. Inclusion criteria are the conditions that must be met by participants, while exclusion criteria are conditions that disqualify participants.

Informed consent: A process in which participants are informed about the risks, benefits, and procedures of a clinical trial, and then sign a document indicating their agreement to participate.

Open-label study: A study in which all participants receive the treatment being tested. This type of study is often used when the treatment is already approved for use.

Protocol: A written plan that outlines the procedures and guidelines for conducting a clinical trial. The protocol is developed by the sponsor and is reviewed by the ethics review board.

Randomization: A process used to assign participants to different groups in a clinical trial. Randomization helps to ensure that the groups are comparable, which is important for obtaining accurate results.

Schedule of events: A timeline that outlines the activities and assessments that are scheduled to take place during a clinical trial.

Study sample: A group of people who are studied in a clinical trial. The study sample is defined by the eligibility criteria and may include people of different ages, genders, and health statuses.

Sponsor: The organization that funds and conducts a clinical trial. The sponsor has ultimate responsibility for the trial's design, conduct, and reporting.

Study coordinator: The person who is responsible for the day-to-day management of a clinical trial. The study coordinator works closely with the principal investigator to ensure that the trial is conducted according to the protocol.

Treatment group: A group of subjects that receive the drug or treatment being tested. The treatment group is compared to the control group to evaluate the treatment's effectiveness.

Clinical trial (clinical study): A research study in which new drugs and treatments are tested on people to evaluate their safety and effectiveness. Clinical trials are typically conducted in phases, with each phase building upon the previous one.

Phases of Clinical Trials:

Phase 1: The first stage of a clinical trial, in which the drug or treatment is tested for safety in a small group of healthy volunteers. Phase 1 trials are typically done to determine the maximum tolerated dose and any side effects of the treatment.

Phase 2: The second stage of a clinical trial, in which the drug or treatment is tested for efficacy in a larger group of patients who have the condition being treated. Phase 2 trials may also be used to further assess the safety of the treatment.

Phase 3: The third stage of a clinical trial, in which the drug or treatment is tested in a large group of patients to confirm its effectiveness and safety. Phase 3 trials are often done in multiple centers to provide more data on the treatment's performance.

Phase 4: The fourth and final stage of a clinical trial, in which the drug or treatment is tested in a real-world setting to evaluate its long-term effects and any rare side effects.

For further information on your condition, visit your community website at [raremark.com](http://raremark.com) to receive the latest news and research for your rare disease.