Community Healthcare System

The Review

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Glossary of Clinical Trial Terms

Protocols and consents can be difficult to understand even for the seasoned professional. This issue provides definitions for the some of the most commonly used terminology in research.

Adjuvant therapy: Treatment given after surgical intervention when no objective evidence of remaining disease exists.

Adverse Event: An unwanted effect that may be caused by the treatment under investigation

Arm: Any of the treatment groups in a randomized trial

Bias: When a point of view prevents impartial judgment. Bias is controlled by blinding and randomization

Blinding: The study design by which the subject and/or the research staff is unaware of the subject's assignment to the treatments being studied.

Causality: The relationship between an adverse event and the investigational treatment.

Certificate of Confidentiality: Protects against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a subject. Most commonly used in biomedical, behavioral, clinical and other forms of sensitive research.

Clinical trial: A systematic study designed to evaluate a product using human subjects, in the treatment, prevention, or diagnosis of a disease or condition, as determined by the product's benefits relative to its risks.

Cohort: A group of individuals with some characteristics in common.

Control group: A comparison group of subjects who are not treated with the investigational agent. The subjects in this group may receive no therapy, a different therapy, standard therapy or a placebo.

Cross-over design study: Each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

Dose-Ranging Study: Two or more doses of an agent (drugs, radiation, etc.) are tested against each other to determine which dose works best and is least harmful.

Double-Blind Study: Neither the subject nor the clinical trial staff knows which subjects are receiving the investigational agent and which are receiving a placebo or another therapy. These are thought to reduce bias.

Interim analysis: An examination of the data, usually at the mid-point of a study, to review safety and/or efficacy and determine whether the study should continue.

Investigators' brochure: A proprietary and confidential summary of the preclinical data of an investigational drug for a specific study that is supplied to all investigators.

Longitudinal Study: study conducted over a long period of time.

Minimal risk: a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the propose research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Non-Inferiority Study: Study designed to question if treatment A is as effective as B or equally ineffective as B.

Off-Label use: A drug or device is used for conditions other than those originally approved by the FDA.

Open-Label or Open Design Study: The subject and clinical research staff are informed of the investigational agent. None of the subjects receive placebos.

Parallel Group design: The treatment and the control is applied simultaneously to two separate groups of subjects.

Phase I Trials: Initial studies to determine the possible side effects of the treatment and to gain early evidence of effectiveness; may include healthy subjects.

Phase II Trials: Controlled clinical studies conducted to evaluate the effectiveness of a treatment for a particular indication in subjects with the condition under study to determine short-term side effects and risks.

Phase III Trials: Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the treatment has been obtained. Is intended to gather additional information to evaluate the overall risk-benefit relationship of the treatment and provide an adequate basis for labeling.

Phase IV Trials: Post-marketing studies to delineate additional information including the treatment's risks, benefits, and optimal use.

Placebo: An inactive substance designed to resemble the investigational agent.

Prevention Trial: Refers to trials to find better ways to prevent disease; may include medicines, vitamins or minerals, vaccines, or lifestyle changes.

Protocol Deviation: An unintended or unapproved change to an IRB approved protocol. Generally does not have a significant effect on the subject's rights, safety, or welfare, or on the integrity of the data. Example: Obtaining a protocol required test one day out of the acceptable "window".

Protocol Violation: Those events that were caused by or could have been prevented by the investigator and which materially affect the study results. Generally affect the subject's rights, safety, or welfare, or the integrity of the data. Example: Enrolling a subject who did not qualify for the trial without obtaining the sponsor's permission or repeatedly failing to obtain a protocol required test.

Prospective studies: Studies designed to observe outcomes or events that occur subsequent to the identification of the group of subjects to be studied. Prospective studies need not involve manipulation or intervention but may be purely observational or involve only the collection of data.

Randomization: A method based on chance by which subjects are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. From what is known at the time, any one of the treatments chosen could be of benefit to the subject.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Retrospective Study: Research conducted by reviewing records or information abut past events elicited through interviews with subjects who have , and controls who do not have, a disease under study.

Standard treatment: The currently accepted treatment or intervention considered to be effective in the treatment of a specific disease or condition.

Study endpoint: A primary or secondary outcome used to judge the effectiveness of a treatment.

Treatment trials: Trials which test new treatments, new combinations of drugs, or new approaches to surgery, devices or radiation therapy.

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