IMPORTANT DEFINITIONS FOR ANALYZING RESEARCH

- **Adverse reaction** - An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time (NLM)

- **Experimental**- In clinical trials, refers to a drug (including a new drug, dose, combination, or route of administration) or procedure that has undergone basic laboratory testing and received approval from the U.S. Food and Drug Administration (FDA) to be tested in human subjects. A drug or procedure may be approved by the FDA for use in one disease or condition, but be considered experimental in other diseases or conditions. Also called investigational. (NCI)

- **Hypothesis**- A supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation. (NLM)

- **Inclusion/exclusion criteria-** The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe. (NLM)

- **Literature Review-** a text of a scholarly paper, which includes the current knowledge including substantive findings, as well as theoretical and methodological contributions to a particular topic. **Literature reviews** are secondary sources, and do not report new or original experimental work.

- **National Institutes of Health**- NIH. A federal agency in the U.S. that conducts biomedical research in its own laboratories; supports the research of non-Federal scientists in universities, medical schools, hospitals, and research institutions throughout the country and abroad; helps in the training of research investigators; and fosters communication of medical information. Access the National Institutes of Health Web site at http://www.nih.gov. Also called NIH. (NCI)

- **Nonblinded-** Describes a clinical trial or other experiment in which the researchers know what treatments are being given to each study subject or experimental group. If human subjects are involved, they know what treatments they are receiving. (NCI)

- **Nonrandomized clinical trial-** A clinical trial in which the participants are not assigned by chance to different treatment groups. Participants may choose which group they want to be in, or they may be assigned to the groups by the researchers. (NCI)

- **Meta-analysis**- The formal evaluation of the quantitative evidence from two or more trials bearing on the same question. This most commonly involves the statistical combination of summary statistics from the various trials, but the term is sometimes also used to refer to the combination of the raw data. (ICH E9)

- **Off-label**

    - Describes the legal use of a prescription drug to treat a disease or condition for which the drug has not been approved by the U.S. Food and Drug Administration. (NCI)

    - A drug prescribed for conditions other than those approved by the FDA. (NLM)

- **Peer review**- Review of a clinical trial by experts chosen by the study sponsor. These experts review the trials for scientific merit, participant safety, and ethical considerations. (NLM)

- **Pilot study**- The initial study examining a new method or treatment. (NCI)

- **Placebo**-

    - A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness. (NLM)
    - An inactive substance or treatment that looks the same as, and is given the same way as, an active drug or treatment being tested. The effects of the active drug or treatment are compared to the effects of the placebo. (NCI)

- **Placebo controlled study**

    - A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition. (NLM)
    - Refers to a clinical study in which the control patients receive a placebo. (NCI)

- **Placebo effect**- A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance. (NLM)

- **Randomization**

    - A method based on chance by which study participants are assigned to a treatment group. Randomization minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant (NLM)
    - When referring to an experiment or clinical trial, the process by which animal or human subjects are assigned by chance to separate groups that compare different treatments or other interventions. Randomization gives each participant an equal chance of being assigned to any of the groups. (NCI)
    - The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias. (ICH E6)

- **Randomized clinical trial**

    - A study in which the participants are assigned by chance to separate groups that compare different treatments; neither the researchers nor the participants can choose which group. Using chance to assign people to groups means that the groups will be similar and that the treatments they receive can be compared objectively. At the time of the trial, it is not known which treatment is best. It is the patient's choice to be in a randomized trial. (NCI)
    - A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilized. (NLM)

- **Single blind study**

    - A type of clinical trial in which only the doctor knows whether a patient is taking the standard treatment or the new treatment being tested. This helps prevent bias in treatment studies. (NCI)

    - A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking; also called single-masked study. (NLM)
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- **Statistical significance**- The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed. (NLM)

- **Uncontrolled study-** A clinical study that lacks a comparison (i.e., a control) group. (NCI)