Clinical Studies

Studies in which scientists do not treat patients

Epidemiological Study

Study of who, what, and how frequently a disease is occurring, and who contracts it. For example, to see how disease is transmitted.

Observational Study

Study of how frequently a new treatment is occurring, and who is experiencing it. Researchers can calculate whether the difference is probably real (statistically significant) or happened by chance. Sometimes an observational study has too few subjects to confidently do the calculation.

Studies in which scientists do treat patients

Clinical Trial

Study to determine whether or not a new treatment should be used in patients with a certain condition, or if a previously approved treatment should be used to treat a condition different than the one it was originally approved for.

Outcomes

Information collected to determine what effect a treatment is having on patients. This helps evaluate the effectiveness of the treatment, and there are severe side effects that could prevent its use.

Features of High Quality Clinical Trials

Controlled

Researchers can compare a cohort of subjects who received the treatment with a control cohort. The control group may be a placebo group, or a control group with other treatment(s) (standard of care). Identifying the only difference between cohorts is the treatment. But people have different age, sex, ethnic, health history, and through trials. These factors can also affect their outcomes.

Randomized

Randomization is when researchers randomly assign subjects to the treatment or placebo cohorts, as if flipping a coin. This is the most reliable way to create cohorts that equalize the different characteristics.

Blinded

In a single-blinded study, subjects are not told which treatment they are receiving. In a double-blinded study, the researchers do not know which is the most rigorous method

Useful definitions for evaluating drug development studies

Useful definitions for evaluating scientific studies on drug development

Type of Preclinical Study

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Preclinical Studies

These studies are used to determine if a treatment might be effective in people and should then be tested in a clinical trial.

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