Common Statistical Terms Used in Clinical Trials

Bias

Systematic tendency of any factors associated with the design, conduct, analysis and evaluation of the results of a clinical trial to make the estimate of a treatment effect deviate from its true value

Equivalence Trial

Trial with primary objective of showing that the response to two or more treatments differs by an amount which is clinically unimportant

Full Analysis Set

Set of subjects that is as close as possible to the ideal implied by the intention-to-treat principle

Generalizability

Extent to which the findings of a clinical trial can be reliably extrapolated from the subjects who participated in the trial to a broader patient population and a broader range of clinical settings

Independent Data Monitoring Committee

May be established by the sponsor to assess at intervals the progress of a clinical trial, safety data, and critical efficacy endpoints, and to recommend whether to continue, modify, or stop a trial

Intention-To-Treat Principle

Principle that asserts that the effect of a treatment policy can be best assessed by evaluating on the basis of the intention to treat a subject rather than the actual treatment given.

Per Protocol Set

Set of data generated by the subset of subjects who complied with the protocol sufficiently to ensure that these data would be likely to exhibit the effects of treatment, according to the underlying scientific model

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Missing Data

Data that would be meaningful for the analysis but were not collected. They should be distinguished from data that do not exist or data that are not considered meaningful

Sensitivity Analysis

Series of analyses conducted with the intent to explore the robustness of inferences from the main estimator to deviations from its underlying modeling assumptions and limitations in the data

Principal Stratification

Classification of subjects according to the potential occurrence of an intercurrent event on all treatments. With two treatments, there are four principal strata with respect to a given intercurrent event

Non-Inferiority Trial

Trial with primary objective of showing that the response to the investigational product is not clinically inferior to a comparative agent

Safety & Tolerability

Safety of a medical product concerns the medical risk to the subject, usually assessed in a clinical trial by laboratory tests, and other special safety tests. The tolerability of the medical product represents the degree to which overt adverse effects can be tolerated by the subject

Superiority Trial

Trial with the primary objective of showing that the response to the investigational product is superior to a comparative agent

Treatment Effect

Effect attributed to a treatment in a clinical trial. In most clinical trials the treatment effect of interest is a comparison (or contrast) of two or more treatments

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