Study design

Clinical study design is the formulation of trials and experiments, as well as observational studies in medical, clinical and other types of research (e.g., epidemiological) involving human beings.

The goal of a clinical study is to assess the safety, efficacy, and / or the mechanism of action of an investigational medicinal product or procedure, or new drug or device that is in development, but potentially not yet approved by a health authority (e.g. Food and Drug Administration). It can also be to investigate a drug, device or procedure that has already been approved but is still in need of further investigation, typically with respect to long-term effects or cost-effectiveness.

Methodological quality refers to the level of rigor and validity in the design, implementation, and analysis of a research study. In other words, it refers to how well a study has been conducted and how confident we can be in its findings.

Some factors that can affect methodological quality include the sampling method, data collection techniques, the use of appropriate measures and statistical analyses, the control of confounding variables, and the reporting of results. A study with high methodological quality is more likely to produce reliable and accurate results and to be considered trustworthy by other researchers and the scientific community.