

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.

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