

## How to write about statistical methods in your research plan?

The following list of instructions is applicable to a good part of clinical research.

1. The aims of the study need to be described in appropriate detail. Examples: the plan needs to specify whether its aim is to show difference between two groups or, alternatively, equivalence of the two groups; is the purpose to show or estimate subject-specific changes in the response/outcome, or to estimate the average between-group difference in the response/outcome.
2. The plan needs to delineate clearly the main response/outcome variable(s).
3. The sample to be collected or used in the study must be clearly defined. The inclusion and exclusion criteria are mentioned.
4. The plan needs to specify which comparison, or quantity to be estimated, the sample size is based. Alternatively, tell why it is conceived that the available sample size is large enough to justify conducting the study. The comparison should be based on the main response/outcome variable. The sample size needs to be based on the actual statistical methods to be used (see point 6 below).

Apart from stating the level of type I and II errors, the input values and parameters that were used in sample size (equivalently power) calculations need to be mentioned (e.g. standard deviation of the response variables in the two comparison groups and the smallest meaningful difference to be shown). Mention the sources of these values (e.g. literature or previous/pilot studies).

5. If the study is a randomised experiment, describe how randomisation has been planned. If the study is observational, describe potential confounders and other sources of bias, as well as the plan for how to adjust and control their impact through study design and/or analytical methods.
6. The main statistical methods (names of hypothesis tests, e.g. t test; type of regression model, e.g. logistic regression or Cox proportional hazards regression) are mentioned. The background variables (confounders) are specified.