



Statistical Consulting Service Sample Size Calculation Guidelines

Clients requesting sample size calculations for prospective studies are required to adhere to the guidelines outlined below. The SCS reserves the right to refuse service until a reasonable attempt has been made in this regard.

Calculation Specifications

- The client should state the desired significance level and power for the test. If these values are not provided, the consultants will either assume 0.05 and 0.8 respectively, or use their discretion on a case by case basis.
- The number of treatment groups and the treatment(s) applicable to each treatment group must be clearly stated.
- The client must explicitly state which treatment groups are compared with which, and by which measure/outcome. In the case that groups are compared according to multiple measures/outcomes, the exact number of these comparisons must be supplied. It should also be clear whether groups are being compared by means or by proportions.
- The type(s) of statistical test(s) must be made clear. If none of the descriptions below is applicable, the client must provide a clear description of the nature of the comparison(s) at hand.
 - Tests for equality test whether there is a difference between two groups and say nothing about the direction of that difference.
 - Tests for superiority/non-inferiority test whether one group is better/worse than the other. In this case, the margin for superiority/non-inferiority must be provided. The client should also clearly state which group is expected to have the higher test statistic.
 - Tests for equivalence compare a single group against some fixed benchmark. This benchmark must be provided.

Calculation Inputs

Sample size calculations typically require inputs that are based on pilot studies, expert intuition, or similar prior works.

In the case of comparisons of means, the calculation requires a mean and a standard deviation for each outcome being compared, for each treatment group. **The client is required to provide these means and standard deviations, or to provide papers which contain enough information for them to be calculated.** These papers must match the treatments and outcomes in question exactly. While this might not be possible for all outcomes in all treatment groups, the more supplied the better.

In the case of comparison of proportions, the calculation requires the relevant proportions of the outcomes under comparison, for each treatment group.

Finding this data can be difficult and time consuming and while consultants are able to provide guidance on what is required, *it is not the responsibility of the consultants to do this research.*

If this information is not provided, the consultants will default to a very rough sample size estimation. *It is the responsibility of the client, and not of the consultants, to ascertain that better information does not exist.*