Multiplicity

Multiplicity occurs in clinical trials when a single clinical trial has several objectives, such as:

- assessing several different doses of a treatment,
- using several different endpoints to measure different aspects of a disease, or
- looking at several different subgroups of patients.

Multiplicity can affect statistical analyses and therefore undermine trial conclusions if it is not addressed.

Multiplicity can increase the Type I error rate. A number of statistical methods can be used to control the Type 1 error rate. The methods to be used in a clinical trial should be detailed in the study protocol or the statistical analysis plan for that trial.