Significance Level

The significance level (or α level) is a threshold that determines whether a study result can be considered statistically significant after performing the planned statistical tests. The significance level is most often set to 5% (or 0.05), although other levels may be used depending on the study. This represents the probability of rejecting the null hypothesis when it is true. For example, a significance level of 0.05 indicates a 5% risk of concluding that a difference between the study results and the null hypothesis exists when there is no actual difference.

The significance level must be stated in the trial protocol as part of the statistics section. The probability of a result being due to chance rather than due to a medicine or other intervention being studied, if the null hypothesis is true (that is, if there is really no true difference), is known as the 'p-value'. A result is then said to be statistically significant if it yields a p-value equal to or less than the significance level and thus will not be considered a chance occurrence. This is generally written as $p \le 0.05$.