

Recommendations concerning statistical analysis, etc.

The editorial board of the Japanese Journal of Generic Medicines

Samples

When study samples are drugs used for medical purposes, give the name of the manufacturer and the lot numbers if possible. If symbols such as “A,” “B,” etc. are used, provide the reason.

Statistics

For comparison between 2 or more groups, it is recommended to prepare the paper taking the following matters concerning data aggregation, statistical analysis, and discussion into consideration:

- 1) The parameter that shows the fluctuation of measured values should basically not be given in standard error, but in standard deviation. It is desirable to show the data distribution visually such as by a Box plot.
- 2) For comparison of the mean between groups,
 - 2-a) Discuss the uniformity of the arrangement of background factors (items) other than the evaluation item between the groups to be compared.

- 2-b) Describe the authors' opinion on how large a difference in the value of the subject indicator has to be considered as a meaningful difference (clinically significant differences).
- 2-c) Describe the justification for the selection of the number of subjects and the number of cases in the study.
- 2-d) Use multiple comparison to compare 3 or more groups.
- 2-e) The p value should not be shown as $p<0.05$ or $p<0.01$, etc; the precise p value should be shown.
- 2-f) For the discussion of results based on statistical tests and statistical estimations, clinically significant differences, the number of data (number of subjects and number of cases), etc. should be considered in addition to the results such as statistical significance tests. Note that the statistical conclusion is not directly connected to clinical “equivalence” or “nonequivalence.” It may help to include and utilize a confidence interval so that a hasty discussion can be avoided.

Please take the recommendations listed above into consideration.