Researchers may also want to compare a parameter from a *first sample* with the same parameter of a *second sample*. This situation occurs in clinical trials where there are two study arms, that is, an experimental drug group and a control group. In the context of a clinical trial, the relevant parameters (mean value of death rate; standard deviation) are collected from the two *samples*. But the relevant *population* parameters (mean value of death rate; standard deviation) would usually be impossible to collect, because this *population* would consist of all of the people in the world having the disease of interest, and satisfying the particular inclusion criteria and exclusion criteria mandated by the trial design.

VI. WHAT CAN BE COMPARED

Tests in drug manufacturing, or comparisons made in clinical trials, often take one of the following three forms (36). First, the mean value from a sample can be compared with a hypothetical value. The hypothetical value can be a standard (manufacturing specification) set forth by the manufacturing industry. The hypothetical can be a value from a census, or from an epidemiological study, involving every person in a country. For this type of study, there is one sample group and one population group.

A second type of comparison can involve paired data. For each subject, a parameter is measured before treatment and after treatment. Thus, each subject serves as his own control. For this type of study, there are two samples (but no population group). The statistical analysis compares the mean value of the "before" measurements, with the mean value of the "after" measurements. Disis et al. (37) provide an excellent example of the statistical analysis of paired data, where immune response in cancer patients was measured before and after vaccination.

Third, the mean value from a first sample can be compared with the mean value of a second sample. With this type of comparison, in the context of clinical trials, the human subjects in the first sample are not the same people as the human subjects in the second sample. This third type of comparison is the most common trial design that is used in randomized clinical trials.

VII. ONE-TAILED TEST VERSUS TWO-TAILED TEST

The terms one-tailed test and two-tailed test are encountered, for example, when conducting analytical studies on manufactured tablets and when conducting clinical trials. When doing calculations, these terms are encountered when plugging a Z-value into a table of areas under the standard normal curve, and acquiring a P value. A one-tailed test is also called a one-sided test, and a two-tailed test is also called a two-sided test.

This standard table has been called, "Standard Normal Distribution Areas" (38),

[36]Whitley E, Bell J. Statistics review 5: comparison of means. Critical Care. 2002;6:424–28.

[37]Disis ML, Wallace DR, Gooley TA, et al. Concurrent trastuzumab and HER2/neu-specific vaccination in patients with metastatic breast cancer. J. Clin. Oncol. 2009;27:4685–92.

[38]Durham TA, Turner JR. Introduction to statistics in pharmaceutical clinical trials. PhP Pharmaceutical Press, Chicago, 2008. pp. 195–203.