

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. One-tailed test is also called one-sided test, and two-tailed test is also called two-sided test.

This standard table has been called “Standard Normal Distribution Areas” (38) “Areas in Tail of the Standard Normal Distribution” (39) and “Areas Under the Standard Normal Curve” (40).

The heading of the table of areas under the standard normal curve typically directs the reader to one column of numbers, which is to be used for one-tailed tests, and to another column of numbers, which is to be used for two-tailed tests (41).

A one-tailed test is used to determine if the mean of group 1 is greater than the mean of group 2, while a two-tailed test is used to determine if the mean of group 1 is different than the mean of group 2 (42). By “different,” what is meant here is whether there is a statistically significant difference. More accurately, by “different,” what is meant is if the difference is plausible within an acceptable degree of error (43).

<sup>37</sup> 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;27:4685–4692.

<sup>38</sup> Durham TA, Turner JR. *Introduction to Statistics in Pharmaceutical Clinical Trials.* Chicago, IL: PhP Pharmaceutical Press; 2008;195–203.

<sup>39</sup> Kirkwood BR, Sterne JA. *Essential Medical Statistics.* 2nd ed. Malden, MA: Blackwell Science Ltd.; 2003;470–471.

<sup>40</sup> Dawson B, Trapp R.G. *Basic and Clinical Biostatistics.* 4th ed. New York, NY: Lange Medical Books; 2004;364–365.

<sup>41</sup> Dawson B, Trapp R.G. *Basic and Clinical Biostatistics.* 4th ed. New York, NY: Lange Medical Books/McGraw-Hill; 2004;364–365.

<sup>42</sup> Norman GR, Streiner DL. *Biostatistics.* 3rd ed. Hamilton, Ontario: B.C. Decker, Inc.; 2008;56.

<sup>43</sup> Elder J. E-mail of May 12, 2011.