TABLE 10.3 Common Critical Values From the Standard Normal Distribution ($z_{1-(\alpha/2)}$ or $z_{1-\beta}$) Based on Choices for α (Alpha) or β (Beta)

α (Type I Error)	β (Type II Error)	$z_{1-(\alpha/2)}$ or $z_{1-\beta}$
0.01	0.005	2.58
0.02	0.01	2.33
0.05	0.025	1.96
0.1	0.05	1.64
0.2	0.1	1.28
0.4	0.2	0.84
0.9	0.45	0.13

Geigy (9). Critical values based on various commonly utilized values of α are reported in Table 10.3. Using this table, we see that when α (alpha) is 0.05 the critical value, $z_{1-(\alpha/2)}$, is 1.96. Plugging in the pieces of information that we have into our formula we have:

$$1.96\frac{\sigma}{\sqrt{50}} = 0.4$$

With some algebraic manipulation, we have:

$$1.96\frac{\sigma}{7.07} = 0.4, \quad 0.28\sigma = 0.4, \quad \sigma = \frac{0.4}{0.28}, \quad \sigma = 1.43$$

Now, we have all the information to calculate the sample size for the new study with the stated requirements for power. Plugging these values into our sample size formula, we see that the required sample size per group is:

$$n = \frac{2(1.43)^2(7.8)}{(-0.5)^2} = 127.60$$

Here, 128 subjects would be needed for each treatment group or the total size of the trial should be 256 subjects.

Suppose the drug company was concerned about the assumption of the mean difference between the treatment groups not being exactly as observed from the previous study. In this case, the company may want to consider a range of reasonable values. Certainly, it would be reasonable to consider the lower and upper limits of the two-sided 95% confidence interval about the mean difference from placebo, (−0.9, −0.1) as plausible values for the value of $\mu_1 - \mu_2$. Using the value of the lower limit of the confidence interval, −0.9, as the value of $\mu_1 - \mu_2$ and holding the other assumptions as before, yields a sample size per group of:

$$n = \frac{2(1.43)^2(7.8)}{(-0.9)^2} = 39.38$$

Similarly, substituting the value of the upper limit of the confidence interval, −0.1, as the value of $\mu_1 - \mu_2$ and holding the other assumptions as before, yields a sample size per group of:

$$n = \frac{2(1.43)^2(7.8)}{(-0.1)^2} = 3190.04$$

VIII. CHANGES IN SAMPLE SIZE ASSUMPTIONS CAN YIELD DRAMATIC CHANGES TO SAMPLE SIZE

It is clear from the examples presented in this section that seemingly small changes in any of the assumptions can lead to very large changes in the sample size necessary to achieve the required power for a trial. The choices of α and β are controlled by the individual or individuals who are initiating the study, and can be varied according to the needs or requirements of the clinical program.

[9] Lentner C, editors. Geigy scientific tables. 8th edition. Vol 2: Introduction to statistics, statistical tables, mathematical formulae. Basle: Ciba-Gigy; 1982. ISBN 0-914168-51-7.