**Title: Testing of hypothesis for various types of clinical trial: Power of the test and sample size determination of clinical trial**

**The formula for sample size determination for two sided test is**

Q1) Suppose, that pharmaceutical company is interested in conducting a clinical trial to compared two cholesterol lowering agents for treatment of hyper cholesterol patients. The primary efficiency parameter is low density lipid protein cholesterol (LDL-C). Suppose that a difference of 8% in the change of (LDL- C) is considered a clinically meaningful difference and that the standard deviations assume to be 15 for given level of significance 5% and 80% power. Calculate Sample size. Write R code for calculating sample size.

**Program:**

Z0.025=qnorm(0.05/2,0,1);Z0.025

**-1.959964**

Z0.2=qnorm(0.2,0,1);Z0.2

**-0.8416212**

delta=8

SD=15

n=2\*(SD^2/delta^2)\*(Z0.025+Z0.2)^2

n

**55.18744**

**For given problem sample size is 56.**

Q2) A pharmaceutical company is intended in examining effect of antidepressant agent in patient which will generalized patient anxiety disorder a double blind two arm parallel placebo control randomize trial is planned to determine required sample size for achieving an 80% power the (HAM-A) score is considered as a primary efficiency variable it is believed that a difference of four in the (HAM-A) scores between the antidepressant and placebo is clinically important. Assume that the standard deviation is 7. Obtain from previous study and α=5%. Calculate sample size.

**Program:**

Z0.025=qnorm(0.05/2,0,1);Z0.025

**-1.959964**

Z0.2=qnorm(0.2,0,1);Z0.2

**-0.8416212**

delta=4

SD=7

n=2\*(SD^2/delta^2)\*(Z0.025+Z0.2)^2

n

**48.07439**

**For given problem sample size is 49.**