

Conditional Power calculation for Group Sequential – Difference of means example:

Suppose we want to calculate conditional power at a 70% interim (210 of 300 in each group) for a group sequential clinical trial where the assumed mean values for the two groups were (75, 70), and the observed values at the interim were (73, 72). Let $\sigma_1 = \sigma_2 = 3$, and $\alpha = 0.05$.

$x_{ij} := \text{observation of subject } j \text{ in treatment group } i \text{ (assume iid and normal)}$

$\mu_1, \mu_2 := \text{assumed alternative hypothesis}$

$\bar{x}_{a,1}, \bar{x}_{a,2} := \text{observed values}$

$\frac{m_i}{n_i} := \text{information fraction}$

At first interim m_i of n_i subjects have been observed. For difference of means:

Let $\bar{x}_{a,i} = \frac{1}{m} \sum_{j=1}^{m_i} x_{ij}$, then using approximation in [1, pg. 188] we calculate conditional power to be $CP = 1 - \Phi(\tau)$,

$$\begin{aligned} \text{where } \tau &= \left[z_{\frac{\alpha}{2}} \sqrt{\frac{\sigma_1^2}{n_1} + \frac{\sigma_2^2}{n_2}} - (\mu_1 - \mu_2) - \left(\frac{m_1}{n_1} (\bar{x}_{a,1} - \mu_1) - \frac{m_2}{n_2} (\bar{x}_{a,2} - \mu_2) \right) \right] \\ &= \left[1.96 \sqrt{\frac{3^2}{300} + \frac{3^2}{300}} - (75 - 70) - (0.7 (73 - 75) - 0.7(72 - 70)) \right] \\ CP &= 1 - \Phi(\tau) \approx 0.957 \end{aligned}$$

Thus the conditional power is 95.7%.

Of course we can use nQuery, R (gsdesign), SAS/STAT (SEQTEST), or other statistical tools to save the manual effort or double check.