Dr Andrzej S. Januszewski – Samples size calculation for clinical trials

1. Mean difference (2 groups)

$$n = \frac{2 * \left(Z_{\alpha} + Z_{\beta}\right)^{2} * SD^{2}}{d^{2}}$$

 Z_{α} = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

 Z_{β} = standard normal derivative for the type 2 error (value from standard normal distribution (mean=0, SD=1); (MS Excel function NORM.INV or NORMSINV)

SD = standard deviation

d = difference between group means

2. Proportion difference (2 groups)

$$n = \frac{(Z_{\alpha} + Z_{\beta})^{2} * p_{c}(1 - p_{c}) + p_{t}(1 - p_{t})}{(p_{c} - p_{t})^{2}}$$

 Z_{α} = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

 Z_{β} = standard normal derivative for the type 2 error (value from standard normal distribution (mean=0, SD=1); (MS Excel function NORM.INV or NORMSINV)

 p_c = proportion of subjects having the event in the control (placebo) group

p_t = proportion of subjects having the event in the treatment group (percent in control group reduced by the treatment)

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3. Questionnaire

$$n = \frac{\frac{Z_{\alpha}^2 p(1-p)}{e^2}}{1 + \left(\frac{Z_{\alpha}^2 p(1-p)}{e^2 N}\right)}$$

 Z_{α} = standard normal derivative for the type 1 error (value from std normal distribution (mean=0, SD=1) (MS Excel function NORM.INV or NORMSINV)

p = response distribution

e = margin of error

N = population size

4. Supplementary calculations

a. Factor to increase sample size for non-compliance

$$\frac{1}{(1-a-b)^2}$$

a = drop-outs proportion

b = drop-ins proportion

b. Factor to increase sample size for loss to follow-up

$$\frac{1}{1-c}$$

c = lost to follow-up proportion