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Sample size in clinical trial

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Abstract

For a clinical trial proper sample size is of utmost importance. Small sample is unable to detect clinically important results and large sample takes huge resources and also often considered unethical. While calculating the required sample size, Type I and Type II errors, power of the test, significance, probability, effect size and variability-all should be considered beforehand. Based on the sampling technique, sample size of a study varies. With simple random sampling technique, sample size is minimum. With increase in sample size, power of a test increases and Type II error (β error) decreases. Study showing significant result in higher confidence interval (at least 95%) also requires sufficient sample size. Effect size is often ignored when clinical trials are conducted. Choice of one sided or two sided test also affects required sample size. Sample size required for equivalence study differs from that required for non-inferiority or superiority design. Based on the available data, (continuous or discrete), sample size differs. There are many formulae for calculating sample size-many a times the researcher faces difficulty in selecting appropriate formula for calculating sample size for his/ her study. It would be better if clinicians themselves are involved in calculating sample size; so that the expected mean difference, difference in proportion etc. can be calculated based on their clinical experience. Both clinicians and statisticians should work hand in hand for the success of a clinical trial done on appropriate number of patients-not very small and not very large.

Biography

Pratyay Pratim Datta after being medical graduate (MBBS) from NRS Medical College, Kolkata, India, completed DPH from All India Institute of Hygiene and Public Health, Kolkata. He has completed professional certificate in Pharmacovigilance, course on Bio-ethics, PG Diploma in Adolescent Health, PG in Health Promotion. He completed Biostatistics and SPSS course, Certificate course on Clinical trial and Meta-analysis and certificate course on linear and logistic regression from CMC Vellore in 2011. His research work on Nephrotoxic Effect of Anti-malarial drugs has got best paper award in 2nd International Conference of Indian Society of Rational Pharmacotherapeutics. Currently, he is pursuing Doctorate of Medicine in Pharmacology in Hi-Tech Medical College, Bhubaneswar, Odisha. Dr. Datta has worked in National Polio Surveillance Project of WHO. He has eight research articles published/ accepted in international indexed journals.