



Sample Size Calculations In Clinical Research

Hansheng Wang

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This text enforces statistical design procedures that ensure the validity, accuracy, reliability, and reproducibility of clinical studies. It illustrates formulas for sample size calculation with selected examples from studies on women's health, oncology, in vivo and in vitro bioequivalence, and the cardiovascular and central nervous systems. Topics of discussion include regulatory requirement, considerations prior to sample size calculation, confounding and interaction, crossover design versus parallel design, subgroup/interim analyses, Fisher's exact test, tests for goodness-of-fit and contingency tables, Cox's proportional hazards model, and comparing variabilities.

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