

Evaluating benefit-risk, handling missing data and a universal sample size formula for clinical trials

November 10, 2021
3:00-4:00pm

This seminar is jointly hosted by the Divisions of Biostatistics & Bioinformatics and the CAPS Methods Core

Combining endpoints hierarchically enables the addressing of various problems in clinical trials, ranging from (a) providing a single metric for evaluating benefit and risk, (b) handling missing data by accounting for the reason for missingness, and (c) accounting for relative priorities of multiple efficacy endpoints. For (c), we provide a universal sample size formula for parallel group trials of fixed or variable length that holds across any kind of endpoint. The method is based on the Mann-Whitney U test of comparing patient data in a pairwise manner, and its extensions by other authors for combining endpoints hierarchically. (The last topic is joint work with Lu Tian of Stanford.)



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