Inference for Randomized Clinical Trials

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Randomization for clinical trials is so common that people generally do not associate it with inference. However, randomization can be used as a basis for inference using randomization tests, and different restricted randomization procedures lead to different test statistics. For procedures that do not fix sample fractions, there are different considerations for sample size and power. When we move to more complicated randomization procedures, such as response-adaptive randomization, maximum likelihood estimators can be biased, and standard asymptotic inferential procedures are not obvious. We review recent work in this area.

Professor William F. Rosenberger is Professor and Chairman of Statistics at George Mason University. He received his Ph.D. in mathematical statistics from George Washington University in 1992 and since then has spent much of his career developing statistical methodology for randomized clinical trials. He has two books on the subject, *Randomization in Clinical Trials: Theory and Practice* (Wiley, 2002), which won the Association of American Publishers Award for the best mathematics/statistics book published that year, and *The Theory of Response-Adaptive Randomization in Clinical Trials* (Wiley, 2006). A Fellow of the American Statistical Association, he has published over 60 refereed papers and serves regularly on data and safety monitoring boards of randomized clinical trials.