JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH

Department of Biostatistics

BIOSTATISTICS SEMINAR,

A New Predictive Paradigm for Subset Analysis of Randomized Clinical Trials

Richard Simon, D. Sc.
R Simon Consulting
Formerly, Director of Biometric Research Program
National Cancer Institute

Abstract:

The current paradigm for randomized clinical trials provides effective protection against type I errors, but a weak basis for defining an intended use population. Use of the eligibility criteria as a basis for inferring “who benefits” from the test treatment in positive clinical trials often results in over-treatment of patient populations, very small average treatment effects and large NNT (number needed to treat for each patient who benefits). I will describe a new predictive paradigm for “subset analysis”. The focus is on development of an internally validated predictive classifier rather than on inference based multiple post-hoc testing. This Predictive Analysis of Clinical Trials can provide a useful supplement to the primary test of the global null hypothesis for using the results of the trial.

Johns Hopkins Bloomberg School of Public Health, Department of Biostatistics
Monday, October 15, 2018, 12:15:1-15, Room W2008 (Refreshments 12:00pm)

For disability access information or listening devices, please contact the Office of Support Services at 410-955-1197 or on the web **www.jhsph.edu/SupportServices. EO/AA**

Dept. of Biostatistics, 615 N. Wolfe Street, Suite E3527 Baltimore, MD 21205