



Greater Cincinnati Chapter

American Statistical Association

Fall Meeting

Our fall 2007 meeting will be held at the Procter & Gamble's Mason Business Center (formerly HCRC) which is located in Mason, OH. Directions follow. The meeting will be held in the Harvard Room on **Tuesday, Nov 27 at 3:30 pm**. The seminar will be presented by Dr. Dan Schnell from P&G on "Evaluation of Covariate Adaptive Randomization by Minimization in a Clinical Trial." Abstract of the talk follows.

Abstract of Talk

Evaluation of Covariate Adaptive Randomization by Minimization in a Clinical Trial **Dan Schnell, PhD**

The RDP-58 trial was a clinical trial to assess the efficacy and safety of a new treatment for ulcerative colitis. In this trial, patients were randomized to either a high dose of an active control (AC) or RDP-58 with a low dose of AC. Five factors were identified as important patient-level baseline variables for stratification of the randomization. Two additional factors were also used: clinical site (CS) and overall study balance. Various minimization algorithms to achieve balance across the 7 factors were explored by simulation. The final algorithm used a weighted squared difference objective function to determine the preferred treatment assignment as each patient was enrolled. Simulations suggested that the using minimization procedure would achieve good balance on all factors. Additional simulation findings suggested that linear mixed effects models with CS as a random effect and treatment and other stratification factors as fixed effects would preserve type I error probability for the test of treatment difference and provide unbiased estimates of treatment differences. A total of 156 and 138 patients were randomized (separately) in Phases A and B, at 52 and 46 study sites respectively. The properties of other possible randomization procedures applied to the actual sequence of patients in this study will be evaluated and compared to the actual randomization outcome.

Dan Schnell obtained his PhD in Statistics from Iowa State University in 1987. He spent seven years as a Mathematical Statistician at US Centers for Disease Control in the Sexually Transmitted Disease/HIV group. In 1994 he joined P&G Pharmaceuticals where he has worked in cardiac, gastro-intestinal and musculoskeletal areas, specializing in Phase I and II clinical development. He has publications in a variety of medical and statistical journals coming out of the work done in clinical trials. Currently, Dan is Section Head, Pharmaceutical Statistics at P&G.

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Directions to the Mason Business Center (8700 S Mason Montgomery Road, Mason OH 45040)

Take I-71 to Exit 19.

- If exiting from I-71 southbound, keep right to stay on ramp towards Mason Montgomery Road and then turn right (north) onto Mason Montgomery Road. P&G's Mason Business Center facility is about 1.1 miles on your right (just past Irwin Simpson Rd). Visitor parking is available at the front of the building.
- If exiting from I-71 northbound, turn left (north) at light off exit ramp onto Mason Road and continue until you go under I-71. The road name will change to Mason Montgomery Road. P&G's Mason Business Center facility is about 1.3 miles on your right (just past Irwin Simpson Rd). Visitor parking is available at the front of the building.

For a map, visit or click on <http://www.google.com> and search for "8700 S Mason Montgomery Road, Mason OH 45040" (quotes can be omitted). Click on links at top of results to see a map.

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