5th ANNUAL PROBABILITY AND STATISTICS DAY AT UMBC

FUNDED BY NATIONAL SECURITY AGENCY

Workshop on
Synergistic Statistics and Graphics in Safety Reviews of Clinical Trials
presented by
Dr. Russ Wolfinger, Director of Scientific Discovery, SAS Institute, Inc.
Dr. Kelci Miclaus, Application Scientist, SAS Institute, Inc.

Friday, April 22, 2011 ◆ 2:00pm – 5:30pm ◆ Room 105, Public Policy Building
Registration is <u>FREE</u> but required! ◆ Registration Deadline: Friday, April 1, 2011
Registration Website: www.umbc.edu/circ/hosting/ProbStatDay2011

Overview

Comprehensive and efficient assessment of drug safety is a critical component of ethical clinical trials. Safety reviews have been greatly aided in recent years by dynamically interactive graphics of various domains of safety data. This half-day workshop shows how to enhance the review process further by tightly integrating powerful analytical methods with well-ordered visual displays and drill-downs. The interplay between statistics and graphics affords insights into the data inaccessible by either approach alone.

Outline

1. Supercharging the Shneiderman Mantra with Statistics
2. Overview of CDISC Standards and their Current and Future Importance
3. Nicardipine Example
4. Demographics Distribution
5. Adverse Events
   a. Incidence Screen with Volcano Plots and Drill Downs
   b. Subject Profiling
   c. Time Windowing
6. Labs
   a. Baseline ANOVA
   b. Shift and Box Plots
   c. Hy's Law Screening and Bubble Plots
7. Cross Domain Clustering and Partial Correlation
8. Predictive Modeling, Cross Validation Model Comparison, and Learning Curves

Software

Analyses from JMP Clinical software will demonstrate the key concepts. Although not required, you are encouraged to bring your own Windows laptop to follow along and explore results. Within 30 days of the workshop, you will need to download a free trial of JMP 9 software from www.jmp.com. An accompanying JMP journal file will be provided containing example data sets and scripts.

Department of MATHEMATICS & STATISTICS

UMBC AN HONORS UNIVERSITY IN MARYLAND