

SDASA Presents

Multiple Comparisons, Multiple Endpoints and Interim Data Monitoring

by Alex Dmitrienko, PhD,
Principal Research Scientist
Eli Lilly and Company

Short Course Outline

The course covers important topics that statisticians and research scientists commonly face while conducting clinical research. Main focus will be on the following:

1. Multiple comparisons and multiple endpoints (8:30am – 12:00pm)
 - Popular multiple tests, including closed, fixed-sequence, resampling-based multiple tests.
 - Analysis of multiple endpoints.
 - Gatekeeping and related strategies.
2. Interim data monitoring (1:00pm-4:30pm)
 - Popular approaches to designing and monitoring group sequential trials (repeated significance and triangular tests).
 - Stochastic curtailment methods (frequentist and Bayesian approaches).

Course Information

The course offers a well-balanced mix of theory and applications. It presents practical advice from experts and discusses regulatory considerations. The discussed statistical methods will be implemented using the SAS software. Clinical trial examples will be used to illustrate the statistical methods.

The course will be based on a recently published book by A. Dmitrienko (Lilly), G. Molenberghs (Limburgs Universitair Centrum, Belgium), C. Chuang-Stein (Pfizer) and W. Offen (Lilly). For more information about the book, please visit its web site at <http://www.sas.com/apps/pubscat/bookdetails.jsp?pc=59390>.

Dmitrienko and co-authors won the prestigious excellence in continuing education award for the short course they offered at the 2005 JSM based on the contents of this book.

Biographical Sketch

Alex Dmitrienko, Ph.D., Principal Research Scientist, Eli Lilly and Company, has been actively involved in biostatistical research and has published papers on multiple testing, group sequential inferences and analysis of safety data in clinical trials. He has recently co-authored and published a book on the analysis of clinical trials ("Analysis of Clinical Trials Using SAS: A Practical Guide", SAS Press) and is currently working on another SAS Press book ("Pharmaceutical Statistics").

Short Course Registration Information

Instructor: Alex Dmitrienko, PhD Principal Research Scientist, Eli Lilly and Company

Title: Multiple Comparisons, Multiple Endpoints and Interim Data Monitoring

Date: January 20, 2006, 8:30 AM – 4:30 PM

Price: \$50 / \$25 for students with valid ID. Parking not included. Add \$10 if RSVP after the 15th.

Location: Center for Molecular Genetics, UCSD School of Medicine

Food and beverages will be provided for those who RSVP and not guaranteed for those who RSVP after January 15th.

Please RSVP and send payment to Bei Zhang by Sunday January 15th, 2006:

Bei Zhang

Amylin Pharmaceuticals, Inc.

9360 Towne Center Drive, Suite 110

San Diego, CA 92121

bei.zhang@amylin.com

For more information please email oralia@ucsd.edu or sheela_talwalker@hotmail.com or visit www.sdasa.org.

This event is proudly organized and sponsored by the San Diego Chapter of the American Statistical Association (SDASA) and partially funded by Amylin Pharmaceutical and SANDS