PROGRAMME OF THE SIXTY-THIRD ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

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NY/NJ Metropolitan Section ~ ~ Statistics Division

AMERICAN STATISTICAL ASSOCIATION

Biopharmaceutical Section

December 3 – December 5, 2007: Three-Day Conference

Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ

Short Courses: – December 6-7, 2007

1 Mixed Models Analysis Of Medical Data Using SAS by Robin Prescott (University of Edinburgh, UK) & Helen Brown (National Health Service, UK)

2. Methods and Software for Bayesian Data Analysis by Professor Bradley P. Carlin, University of Minnesota

REGISTRATION WILL BE ON THE FOURTH FLOOR OF THE HAVANA TOWER.
It will start at 6:00 pm on Sunday December 2nd and will be followed by a one-hour reception with cold drinks and snacks.
ALL REGISTRANTS WILL RECEIVE A BOUND COPY OF THE AVAILABLE HANDOUTS FOR ALL SESSIONS.
CEU AWARDED ON REQUEST.
See registration page and website: www.demingconference.com for further details.
You can register for the conference as well as reserve a room at the Tropicana at this site.

Walter R. Young
Chairman
16 Harrow Circle
Wayne, PA 19087

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ASQ

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- The conference will use the meeting facilities in the Tropicana's brand new Havana Tower where attendees will stay in soundproof rooms with climate control, direct-dial phones, cable color TV, coffee makers, hairdryers, refrigerators and gorgeous views of the Atlantic City skyline. Use the separate Havana Tower parking garage on Brighton Ave. for valet or indoor self-parking, $5 for unlimited entry and exit.
- There is a guest check in desk on the 3rd floor of the Havana Tower and all meeting facilities are on the 4th floor.
- It is the largest hotel in the state of New Jersey, with elegant public areas with exclusive retail shops and fine dining.
- It is on the beach with a fully equipped fitness facility (free for conference registrants) and a heated indoor pool.
- The casino is in a separate building connected by a bridge over Pacific Avenue.
- A free Diamond Club Card can offer rewards based on your play and may offer dining and show discounts.
- Go to www.tropicana.net/index2.htm for a complete hotel and Havana Tower description and shows scheduled during the conference.

Travel back to Old Havana, where the queen of all resort hotels—the Tropicana—stood proudly at the heart of it all. Today the Tropicana Casino and Resort recreates a bit of Old Havana with the most extraordinary destination in the history of Atlantic City. World-class dining, non-stop entertainment, a dazzling array of upscale shops and experiences and south Jersey's only IMAX Theatre. You'll find all of this and more at The Quarter that features shopping, dining, theater and spa services in a state-of-the-art complex with 500 hotel rooms.

Tutorial Speakers

Peter Bruce is president of statistics.com, the leading provider of online continuing education in statistics. He has also worked at Cytel Software Corp. and is the developer of Resampling Stats software.

Mark Chang is a director of Biostatistics at Millennium Pharmaceuticals, Inc. He has 17 years experience in teaching, research, and pharmaceutical industry. As the director and head of the Research Biostatistics and Oncology Statistics, his involvements in drug development include both strategic and methodological aspects. His recent researches focus on adaptive designs. He co-authored *Adaptive Design Methods in Clinical Trials* with Shein-Chung Chow. His research interests include statistics, artificial intelligence, and software development.

M. Ashraf Chaudhary is an Associate Scientist (Biostatistics) at the Department of International Health, Johns Hopkins Bloomberg School of Public Health. He has a Biostatistics PhD from the University of North Carolina at Chapel Hill. His current research interests include statistical computing and the design and analysis of randomized clinical trials evaluating novel interventions for the prevention of TB and HIV-AIDS. He has authored more than 30 articles in statistical methodology and collaborative research in various biomedical areas.

Michael Chernick has a PhD in Statistics from Stanford University. He subsequently worked in the aerospace, medical insurance, medical devices and pharmaceutical industries along with a number of teaching and government appointments. In 1983 he won the Wolfowitz prize for the best theoretical paper in the American Journal of Mathematical and Management Sciences and in 2001 he was elected a Fellow of the ASA.

Mike Daniels is Associate Professor of Biostatistics and Statistics and Division Chief of Biostatistics at the University of Florida. He is a fellow of the ASA. His research interests of late have focused on Bayesian methodology for (incomplete) longitudinal data. He currently serves on the editorial boards of Biometrics and JASA.

Norman Draper obtained a BA in Mathematics at Cambridge University in the UK in 1954 and a PhD in Statistics at the University of North Carolina in 1958. After two years working on polyethylene for Imperial Chemical Industries in the UK, he visited the University of Wisconsin 1960-61 and then spent 1961-99 in the Statistics Department there. He is now Emeritus Professor. He is co-author (with Harry Smith) of *Applied Regression Analysis*, 3rd edition 1998.

Feifang Hu is an Associate Professor, Department of Statistics at the University of Virginia, and Division of Biostatistics and Epidemiology, Department of Health Evaluation Sciences, University of Virginia School of Medicine. Dr Hu's research areas of interest include response-adaptive designs in clinical trial, applied probability and statistical inference, and resampling methods. He has authored more than 40 articles in statistical methodology.

Joseph Hogan is Associate Professor and Graduate Program Director in Biostatistics at Brown University. He conducts research on missing data, causal inference, HIV/AIDS and behavioral sciences. He teaches both introductory and advanced courses in Biostatistics. He currently serves on the editorial boards of Biostatistics and Lifetime Data Analysis.

H.M. James Hung is Director of Division of Biometrics I, CDER, FDA. The division provides services for three medical divisions of drug products (cardiovascular and renal, neurology, psychiatry). During his 19 year tenure with FDA, he reviewed many large mortality/morbidity trials in cardiovascular-renal areas. Dr. Hung published in Biometrics, Statistics in Medicine, Controlled Clinical Trials, Biometrical Journal, etc. His research covers factorial design trials, utility of p-value distribution, adaptive design/analysis, and non-inferiority trials.

Anastasia Ivanova is an Associate Professor of Biostatistics at the University of North Carolina at Chapel Hill. Dr. Ivanova's areas of interest include dose-finding and sequential adaptive designs. She has been involved in the design and analysis of clinical trials at the Lineberger Comprehensive Cancer Center since she joined UNC in 1999. She has authored more than 30 articles in statistical methodology and 8 chapters on sequential and dose-finding designs.

Bruce Levin is Professor and Chair of the Department of Biostatistics at Columbia University. Dr. Levin has an interest in statistical methodology for clinical trials, public health, and the law. He is the senior statistical consultant on several multicenter randomized clinical trials in the fields of neurology and cardiology. He creates innovative trial designs like sequential phase II trials that combine selection methods with non-superiority (futility) testing. Dr. Levin also serves as an expert statistical witness in court cases, and is co-author with M.O. Finkelstein of the textbook *Statistics for Lawyers*.

Tanzy Love is a Visiting Assistant Professor at Carnegie Mellon University in the Statistics Department. Dr. Love received her PhD in 2005 from Iowa State University in the Department of Statistics. Her thesis was on methods for microarray data including combining multiple scans and clustering based on posterior expression ratio distributions for maize embryogenesis experiments. Her research interests include Bayesian mixed membership models and other clustering methods for biological applications, methods for quantitative trait loci and bioinformatics, and social network modeling.

Myunghee Cho Paik is Professor of Biostatistics at Columbia University. Dr. Paik's interests are in statistical methodology for clustered data, longitudinal data, missing data and randomized behavioral intervention trials. She has been involved in studies of neurological diseases for the last fifteen years.

Nitin R. Patel holds a Ph.D degree in Operations Research from MIT. He founded Cytel, along with Dr. Cyrus Mehta, in 1987 where he is currently Chairman and Chief Technology Officer. Dr. Patel has been a visiting professor at MIT since 1995. He has published over sixty papers in the areas of statistics, operations research and computing in leading professional journals. Dr. Patel is a Fellow of the American Statistical Association. He is also a Fellow of the Computer Society of India and has served as Vice President of the International Federation of Operational Research Societies.

M. M. SHOUKRI is a Principal Scientist and the Acting Chairman of The Department of Biostatistics and Epidemiology at the Research Center of King Faisal Specialist Hospital. Dr. Shoukri taught applied statistics at Simon Fraser University, the University of British Columbia, and the University of Windsor and was a Full Professor with tenure at the University of Guelph, Ontario Canada. He published in many statistical journals. He is a Fellow of the Royal Statistical Society of London and a member of the International Statistical Institute.

Sue-Jane Wang is Associate Director in the Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research, FDA. Dr. Wang's research interest and publications in recent years have been focusing on adaptive/flexible clinical trial designs, noninferiority active controlled trials,

Monday December 3, 2007
8:30 – 11:30 AM

Session A

Essential Considerations in Non-inferiority Clinical Trial Design & Methodology

Speakers: Drs. H. M. James Hung and Sue-Jane Wang

U.S. Food and Drug Administration

Moderator: William Wang

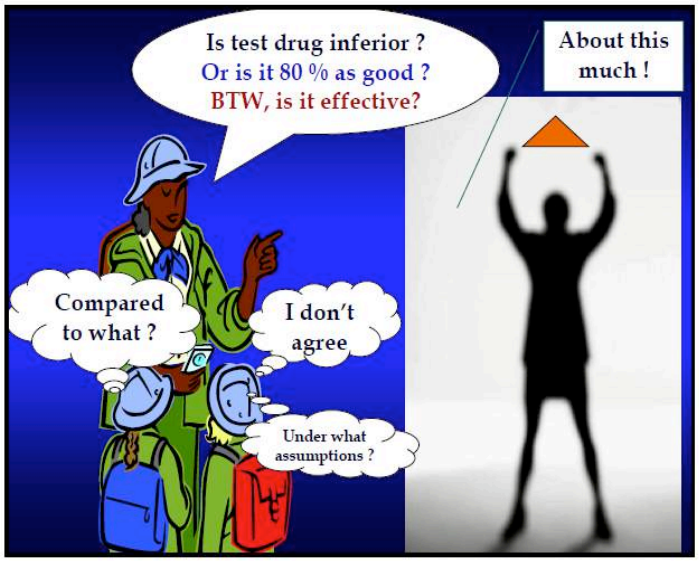
Availability of standard of care and ethical considerations, among others, have prompted vested interests from the clinical development community in seeking designs that aim to address the primary objective that an experimental agent is not substantially inferior to a selected therapeutic agent from the standard of care. The selected agent is often known as an active control serving as the comparator for the experimental agent in an active controlled non-inferiority clinical trial.

This tutorial will provide an overview of essential design specifications and outline some fundamental issues in design and analysis of non-inferiority trials. The tutorial will focus on the challenges in applications for evaluation of drug products. Some typical clinical trial examples will be used for the illustrative purpose.

This all day tutorial, with a ninety minute break for lunch, will cover:

1. Study objectives of an active controlled trial
2. Relevant parameters of primary interest
3. Key assumptions & their implications to study design & statistical analysis
4. Statistical hypotheses associated with the study objectives
5. Design & data elements needed to define a non-inferiority margin
6. Types of non-inferiority margin
7. Choice of scale in defining non-inferiority margins
8. Problems with selecting a NI margin
9. Non-inferiority inference
10. Statistical methods for non-inferiority inference
11. Statistical risks or errors associated with a false assertion
12. Typical case study examples
13. Testing superiority and non-inferiority
14. Design of active controlled trials
15. Challenges and barriers to the planning of non-inferiority trial

It is assumed that the attendees are familiar with clinical trials, statistical hypothesis testing, type I error and confidence interval.



Session B📖

Statistical Methods for Rates and Proportions

Speakers: Professors Bruce Levin and Myunghee Paik

Department of Biostatistics, Columbia University

Moderator: Nandita Biswas

We will discuss topics in the analysis of categorical data via selected chapters of the text. The emphasis will be on conceptual understanding and some computer implementation of analyses. Topics will include: Statistical Inference for a Single Proportion (Chapter 2): Definitions of two-tailed p-values for discrete, asymmetrical distributions; how to accomplish what mid-p does without cheating.

The Effect of Randomness in True Proportions (Chapter 9, Section 6): Estimation of the marginal mean proportion; components of variation; general empirical Bayes estimation of posterior odds; a test of homogeneity of proportions in the large sparse case.

Combining Evidence from Fourfold Tables (Chapter 10): The Cochran-Mantel-Haenszel approach in fixed and random effects meta-analysis; potential confounding versus operational non-confounding; tests of odds ratio homogeneity in the large sparse case.

Logistic Regression (Chapter 11): History, terminology, log-linear models versus logistic regression. Polytomous logistic regression, general logistic regression for exponential families.

The Analysis of Correlated Binary Data (Chapter 15): Adjusted inference for correlation in simple contingency tables and logistic regression procedures; Sample size determination with clustering.

Missing Data (Chapter 16): Definition of missing mechanisms and missing patterns; approaches to handle Mantel-Haenszel procedure and logistic regression under different missing mechanisms.

Monday Lunch (On Your Own) 11:30 AM - 1:00 PM

1:00 - 4:00 PM

Session D📖

Introduction to Data Mining Concepts and Methods

Speakers: Dr. Nitin R. Patel and Peter C. Bruce

Cytel, Inc. and statistics.com

Moderator: Nandita Biswas

This course introduces the rapidly growing multidisciplinary field of data mining. Data mining has evolved from a confluence of ideas from statistics and computer science (machine learning and database methods) applied to large databases in science, engineering, business and government. It first gained momentum primarily from its application to customer relationship management in business but now is beginning to see major applications in the life sciences, finance, and security. The aim of this course is to provide an understanding of the types of problems addressed by data mining and the core concepts that underlie its approach. We will discuss data mining techniques for supervised learning in which outcomes of interest (disease diagnosis, business bankruptcy, response to a direct marketing offer, etc.) are predicted using models trained on past data where the outcomes are known. Popular methods such as classification and regression trees, neural nets, naïve-Bayes, and k-nearest neighbors will be introduced. We will also explore data mining techniques for unsupervised learning - these include hierarchical and non-hierarchical clustering (used in customer segmentation, analysis of microarray data and many other applications), and association rules (used in recommender systems of the type: "If you bought X you will like Y"). Key techniques will be illustrated using XLMiner, an Excel add-in software that was specifically designed by the instructors of this course to provide an affordable vehicle for hands-on learning of data mining.

Session Titles with 📖 are based on a book that is described on the book page and which is available from the conference.

7 PM Speaker's Dinner (Extra Fee Event)

Tuesday December 4, 2007
8:30 – 11:30 AM

Session E📖

Missing Data in Longitudinal Studies

Speaker: Professors Michael Daniels and Joseph W. Hogan
University of Florida and Brown University

Moderator: Jackie Kennedy

This tutorial provides a survey of modern model-based approaches to handling dropout in longitudinal studies, and illustrates the use of newly developed methods for sensitivity analysis and incorporation of prior information. The emphasis is on Bayesian approaches but the models and methods discussed can be implemented in non-Bayesian settings as well. The tutorial will begin with a brief review of models for longitudinal data and the basics of Bayesian inference. Included in this will be a quick primer on the WinBUGS software, used throughout the tutorial to illustrate the concepts and models on real data examples. The second part of the tutorial will focus on dropout. We will discuss formal classifications of the dropout mechanism and describe different classes of models to adjust for biases caused by dropout. Models for both `ignorable' and `non-ignorable' dropout will be covered. The final part of the tutorial focuses on nonignorable dropout. We will describe and motivate principles that should guide assessment of sensitivity to missing data assumptions and appropriate use of prior information. Attendees should have a working knowledge of generalized linear models and statistical inference at the master's level.

Session F📖

Analysis of Correlated Data with SAS and R

Speakers: Professors M. M. Shoukri and M.A. Chaudhary
King Faisal Specialist Hospital and Johns Hopkins University

Moderator: Nandita Biswas

Correlated data arise in clinical and biomedical research, particularly when the sampling units are comprised of clusters. Because of the wide spread use of the cluster design an extensive body of literature on the statistical methods for the analysis of clustered data has emerged. This lecture provides an overview on the analysis of correlated data under cluster sampling design. The fundamental ideas will be illustrated by real life worked examples. Specifically we cover:

1) Analysis of Continuous Data

a. Impact of cluster sampling on the design & analysis of normally correlated data
b. Estimation of the Intra-cluster correlation
c. The Linear Mixed model and the GEE
The analysis of Miall and Oldham family data
d. Sample size estimation under cluster randomization

2) Analysis of Categorical Data

a. Statistical inference from 2x2 table, and adjustment to χ^2 test.
b. Estimation of the odds ratio.
c. Logistic regression and the analysis of the BLV-BIV data.

3) Analysis of Longitudinal Data

a. Poisson Count data
b. The General linear mixed model and the GEE
c. The analysis of the Epilepsy data

4) Analysis of Correlated Survival data

a. The extension of the Cox model
b. Frailty models
c. The analysis of age-at-culling data

Tuesday Lunch (On Your Own) 11:30 AM - 1:00 PM

1:00 - 4:00 PM

Session G📖

Response-Adaptive Randomization in Clinical Trials (RAR): Theory and Application

Speaker: Professor Feifang Hu
Department of Statistics, School of Medicine, University of Virginia

Moderator: Jackie Kennedy

In clinical trials, the fundamental question is: Can we design a clinical trial that is fully randomized, fully powered, can be analyzed using standard tests, and achieves some other important objective? These objectives include, but are not limited to: (i) minimizing the total sample size; (ii) minimizing the total number of expected treatment failures in binary response trials; and (iii) minimizing total cost of the trial if cost per patient differs among treatments. Such problems are in the class of multi-objective optimization problems, which can be solved using standard mathematical optimization techniques. In this talk, we introduce a family of response-adaptive randomization (RAR), doubly adaptive biased coin designs, which can be used to solve the above fundamental question.

In this talk, we present a firm mathematical basis for the use of RAR procedures in practice. We answer important questions, including:

(1). How does RAR affect power?
(2). Can standard inferential tests be applied following RAR?
(3). What is the effect of delayed responses?
(4). Which method is most appropriate and how to quantify its appropriateness?
(5). How can heterogeneity of the patient population be incorporated?
(6). Can one use RAR with more than 2 treatments or with continuous responses?
(7). When is RAR appropriate?
(8). Determine the sample size of a RAR procedure?

We also discuss the following main features of RAR: (I). In clinical trials with a clear treatment effect, reductions in treatment failures can be achieved with no loss of power. (II). In clinical trials with grave outcomes, affecting the outcome of even a single patient, without sacrificing the information gained from the trial, can be a significant contribution from an ethical standpoint. (III). RAR procedures can increase the potential for patient recruitment. (IV). The optimization framework allows us to minimize the total sample size or other costs associated with the clinical trial. (V). The advent of centralized computer randomization with real-time data updates makes such trials easier to implement

Session H📖

Response Surfaces, Mixtures, and Ridge Analyses

Speaker: Professor N. R. Draper
Statistics Department, University of Wisconsin - Madison

Moderator: Walter R. Young

This book, coauthored with George Box is the second edition of one with a different title by the same authors, the 1987 volume *Empirical Model-Building and Response Surfaces*. Known errors were corrected and the material was updated and substantive additions made. Six new chapters and many new exercises were added. (Solutions to nearly all exercises are provided.) The original 42-page bibliography has been expanded to 93 pages. The revised work now has 857 pages, 208 more than the first edition.

Chapter 5, on two-level designs, has received the most changes. The completely new Chapter 12 is a full discussion of ridge regression, a technique that enables a global maximum path, a global minimum path or any intermediate local optima paths to be easily followed on a second degree fitted surface, no matter how many dimensions are involved. Three new chapters, 16-18, introduce the topic of mixture experiments. This sets the scene for new Chapter 19, which explains how to carry out ridge regression on second degree fitted surfaces, not only in a mixture space, but also in any space where linear restrictions need to be enforced, including or not including, as the case may be, the mixture restriction. MINITAB programs for carrying out the calculations have been provided. Chapter 20 shows how to re-formulate the method of canonical reduction in situations where linear restrictions exist on the response.

The tutorial will provide a discussion of the book's new material.

Wednesday December 5, 2007
8:30 – 11:30 AM

Session I📖

Adaptive Designs for Dose Finding Trials
Speaker: Professor Anastasia Ivanova
University of North Carolina at Chapel Hill
Moderator: Fred Balch

Adaptive designs have garnered a lot of attention recently. Dose-finding trials are good candidates for using adaptive designs for this reason; in dose-finding trials, the major emphasis is on estimation, rather than hypothesis testing. In some therapeutical areas such as oncology, adaptive dose-finding designs have been used for years for ethical reasons. In other pharmaceutical areas, adaptive designs might be considered as an alternative to conventional methods if the response can be observed relatively quickly. The 'adaptation' can be done in one or both of the following ways: The first is the 'adaptive' allocation to treatment or doses in order to improve the quality of estimation. The second involves the sequential monitoring of a trial so that it may be stopped early for apparent futility or efficacy. In this tutorial, we will first review adaptive strategies for dose-finding trials, and then examine two areas of application. The first application concerns dose-finding trials in oncology dose-finding trials. The second concerns dose-finding trials in non-life threatening diseases. Both areas of application will be illustrated with real life examples. In this tutorial, among others, we will cover the following topics:

- Escalation and A+B designs
- Up-and-down designs
- CRM and other parametric designs
- Dose finding with delayed outcome
- Dose finding with ordinal and continuous outcomes
- Dose finding with placebo comparator.

Session J

Introduction to Statistical Microarray Analysis
Speaker: Professor Tanzy Love, Carnegie Mellon University
Moderator: Kalyan Ghosh

Many statisticians and medical researchers have heard of microarrays and related genomic technologies. These high-throughput biological methods hold the ability to record data from thousands of genetic sequences at once and statistically analyze and identify a few highly promising candidates for future intensive study. However, the execution of microarray experiments creates high dimensional, correlated data with several levels of experimentally induced bias. As a result, suitable experimental design, image processing, and multiple comparison techniques are needed to extract worthwhile conclusions from microarray experiments. These experiments are being used in many applications including studying the genes related to differential drug response (pharmacogenomics) and differential disease progression. The presentation will assume some exposure to the basic biology of gene expression, though the technology of microarrays will be briefly reviewed. The tutorial's goal is to introduce the statistical concerns and methods associated with microarray experimentation. In this tutorial, we will survey the current statistical techniques used in microarray experimental design and analysis. We will cover the basic technology and biology of microarray analysis, image processing and normalization, differential expression detection, and experimental design for both two-color microarrays and Affymetrix microarrays. Time permitting, we will also touch on adjustments for other common operator errors, time course analysis, and clustering of microarray data. Examples of the methods discussed will be shown, primarily in R, and students will be able to download the programs to run themselves, however there will not be time for this during the tutorial. All necessary R code for examples will be made available on the web

Session K📖

Adaptive Design Theory and Implementation Using SAS and R
Speaker: Dr. Mark Chang, Millennium Pharmaceuticals, Inc.
Moderator: Ivan Chan

The drug development is moving from classic static approaches to adaptive approaches. An adaptive trial design is a design that allows for modifications to the on-going trial based on either the observed data from the trial or external information. In the past several years, there are explosions of adaptive design literatures, which have caused some confusions regarding which methods should be used in which conditions, and how. The tutorial will summarize the major adaptive design methods with an emphasis on the relationships between them. It is intended to give you a clear picture about the different methods. Based on different adaptive design methods, SAS macros and R functions are developed for sample-size re-estimation, drop-loser design, biomarker-adaptive design, and response-adaptive randomization. All the programs will be made available at the workshop and trial design examples will be demonstrated using the programs. Controversies surrounding adaptive designs and practical challenges will be addressed followed by recommendations. The objectives of the tutorial are to teach the hands-on adaptive design techniques from planning, designing, monitoring, and reporting perspectives. Ultimately, the attendees are expected to walk away with the right knowledge, skill, and tools for designing adaptive trials.

Session L📖

Bootstrap Methods for Practitioners and Researchers
Speaker: Dr. Michael Chernick
United Biosource Corporation, Newtown, PA
Moderator: Fred Balch

This tutorial provides an update on bootstrap methods over the nine years that have past since the first edition of the author's text. The presentation will provide introductory material on the nonparametric bootstrap and the application of the bootstrap to confidence intervals and hypothesis testing in addition to variance estimates. This part of the tutorial is not new and was included in the first edition. The first edition presented a number of applications and several examples where the bootstrap fails to be consistent. We shall show results that provide remedies to the consistency problem based on an m out of n bootstrap. Recent important applications to clinical trials include individual and population bioequivalence. The increasing use of multiple endpoints in clinical trials means that the p-value adjustment is becoming, along with closed hypothesis testing, common ways to appropriately address the issue. The existence of the MULTTEST procedure in SAS makes the implementation of bootstrap p-value adjustment much more commonplace. These applications will all be presented.

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TWO SIMULTANEOUS SHORT COURSES
THURSDAY AND FRIDAY, DECEMBER 6-7, 2007
GENERAL COURSE INFORMATION

Registration includes (1) two refreshment breaks each day; (2) handouts and; (3) textbook. No registrations will be accepted without payment in full. Government employees may request to be invoiced at our on-site fee. We will refund tuition if courses are canceled due to insufficient registration.

SCHEDULE

8:30–10:00 Lecture 10:00–10:20 Break 10:20–11:50 Lecture 11:50–1:10 Lunch 1:10–2:40 Lecture 2:40–3:00 Break 3:00–4:30 Lecture
Friday schedule will be a half hour earlier to facilitate students' transportation home

Mixed Models Analysis Of Medical Data Using SAS

Instructors: Robin Prescott (University of Edinburgh, UK)
Helen Brown (National Health Service, UK)
Moderator: Alfred H. Balch

Text: Applied Mixed Models in Medicine

This course will cover the statistical background to mixed models and will emphasise its practical application in medical data with particular reference to clinical trials. All analyses will be illustrated using SAS and lectures will be combined with practical sessions in order to reinforce concepts.

Conventionally, clinical data has been analysed using fixed effects models. However, benefits can often be gained by using a mixed model. For example: in repeated measures trials full allowance can be made for the correlation occurring between the repeated observations even if data are missing; in multi-centre trials or meta analyses treatment standard errors are more appropriately based on between centre/trial variation (fixed effects standard errors are based on within centre/trial variation); in crossover trials more accurate treatment means are often achieved by combining within and between patient estimates. Suitable procedures are now readily available for fitting these models in well-known packages such as SAS. This has led to widespread application and knowledge of mixed models becoming essential for medical statisticians. As with any statistical technique a firm understanding of the theoretical background is essential to allow its effective application and to obtain a clear interpretation of results.

Day 1 of the course will cover:

- General concepts and underlying statistical theory
- Use and interpretation of PROC MIXED
- Multi-centre trials and meta-analysis
- Consideration of issues such as biased standard errors, significance testing and negative variance components
- Repeated measures trials

Day 2 of the course will cover:

- Random coefficients models
- Introduction to Bayesian methods
- Crossover trials
- More complex trial designs
- Generalised linear mixed models

Robin Prescott is Director of the Medical Statistics Unit of The University of Edinburgh and is Professor of Health Technology Assessment. He has been working in the medical field for over thirty years and has a particular interest in cross-over trials. He has wide experience of multi-centre trials and of working with the pharmaceutical industry.

Helen Brown is a Principal Statistician in the National Health Service. She has over twenty years of practical experience as a statistician including five spent in the pharmaceutical industry.

Methods and Software for Bayesian Data Analysis

Instructor: Professor Bradley P. Carlin, University of Minnesota
Moderator: Ivan Chan

Text: Bayes and Empirical Bayes Methods for Data Analysis, 2nd Ed.

Hierarchical Bayes methods enable the combining of information from similar and independent experiments, yielding improved inference for both individual and shared model characteristics. As a result of recent advances in computing and the consequent ability to evaluate complex models, Bayesian methods have increased in popularity in data analysis. This course introduces hierarchical and empirical Bayes methods, demonstrates their usefulness in challenging applied settings, and shows how they can be implemented using modern Markov chain Monte Carlo (MCMC) computational methods. We also provide an introduction and lab demonstration of WinBUGS, the most general Bayesian software package available to date. Use of the methods will be demonstrated in advanced high-dimensional model settings (e.g., nonlinear longitudinal modeling or clinical trial design and analysis), where the MCMC Bayesian approach often provides the only feasible alternative that incorporates all relevant model features. We will pay particular attention to issues of Bayesian design (sample size and power calculations) in both drug and device clinical trials.

Short course participants should have an M.S. (or advanced undergraduate) understanding of mathematical statistics at, say, the Hogg and Craig (1978) level. Basic familiarity with common statistical models (e.g., the linear regression model) and computing will be assumed, but we will not assume any significant previous exposure to Bayesian methods or Bayesian computing. The course is generally aimed at students and practicing statisticians who are intrigued by all the fuss about Bayes and Gibbs, but who may still mistrust the approach as theoretically mysterious and practically cumbersome.

Short course participants are invited to bring their own laptop computers to the session, and to have the latest versions of WinBUGS and R already installed on these computers. Both of these programs are freely available from www.mrc-bsu.cam.ac.uk/bugs/winbugs/contents.shtml and www.r-project.org/ respectively.

The course's goal is to make hierarchical Bayesian methods come alive in the software through real data examples that the participants try for themselves during two afternoon laboratory sessions. All necessary WinBUGS and BRugs code will be made available on the web.

Brad Carlin is Mayo Professor of Public Health and Professor of Biostatistics in the School of Public Health at the University of Minnesota. He has published two textbooks and more than 100 papers in refereed books and journals. In 2000, he was presented with the American Public Health Association's Mortimer Spiegelman Award, awarded for outstanding contributions in health statistics by a statistician under age 40. Most recently, he has been named editor-in-chief of *Bayesian Analysis*, the official journal of the International Society for Bayesian Analysis (ISBA). For more information on Professor Carlin, please visit www.biostat.umn.edu/~brad/

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***Walter R. Young has chaired the Deming conference for thirty-eight consecutive years.**

HOTEL AND CONFERENCE REGISTRATION

Please register online at www.demingconference.com. This gives you an instant e-mail acknowledgement. Pay online with a credit card or mail a check for the amount of your bill in your acknowledgement. If necessary, you may mail or FAX this form.

Please register as early as possible. Payment must accompany this form either by check, which must be included, or by credit card number. You may pre-register with invoices, but will be billed at the on site rate. Make checks payable to "ASQ NY/NJ Metropolitan Section". The American Society for Quality (ASQ) is a tax-exempt organization. Federal Tax ID #39-09-12502. RECEIPTS and a CERTIFICATE OF ATTENDANCE will be distributed at the conference. E-Mail confirmation will be sent

Conference registration starts at 6 PM on Sunday December 2nd, 7:30 AM December 3rd through December 5th and 8 AM on December 6th. Transmit payments and mail registration to Mr. Eric Grossman, New York City Transit, P.O. Box 450, Deer Park, NY 11729
You may FAX a **copy** of the registration form to: (631) 254-6623. **Do Not Attempt to FAX the Orange Form as this Does Not Work**.

Last Name:_____ First Name:_____ Mr. ❑ Ms. ❑ Mrs. ❑ Dr. ❑ Other ❑

Organization Name:_____ Mailing Address:_____

City:_____ State:_____ Zip: _____

Daytime Telephone:_____Facsimile:_____ E-mail:_____

Please Indicate Which Tutorial Sessions You Plan to Attend **A ❑ B ❑ D ❑ E ❑ F ❑ G ❑ H ❑ I ❑ J ❑ K ❑ L ❑ G ❑**

Conference Registration:	**On or Before Oct 1st**	**On or Before Nov 1st**	**After Nov 1st**	**Amount**
Conference	$500	$585	$670	_____
One Day Registration, Monday, Tuesday, or Wednesday (circle 1)	$250	$285	$320	_____
Student (Proof of full time college status needed) or Retiree	$200	$240	$280	_____
One-Hour Registrant Reception with cold drinks & snacks Sunday 6:30 PM	**Free**		**Check box**	❑
Speaker Dinner, Monday 7:00 PM	40	$45	50	_____
Short Course Registration:	$675	$740	$805 *	_____

❑ **Mixed Models Analysis Of Medical Data Using SAS**
❑ **Methods and Software for Bayesian Data Analysis**

Book Order Total (see reverse page) _____

Havana Tower Rate: $ 93.00 (Plus 14% Tax & $ 5 Occupancy Fee & $1 Phone = $112.02) Per Room/Night
Arrival December _____ # of Nights: ___ Smoking?: _____ King or 2 Queen Beds ?: _____
Rooms Must Be Reserved With this Form or on our Web Site on or Before November 19th to Receive the Conference $112.02 Rate
Tropicana Room Reservation (One Night Deposit of $112.02) Cancellation Policy: 48 Hours Prior to Arrival _____
Total Registration, Book Order and Hotel Deposit _____
To Aid in Possible Carpooling to Airport Enter Airport and Flight Arrival and Departure Times With Dates Matching Hotel Reservation
Airport: _____ Arrival: _____ Departure: _____

Cancellations will be accepted until November 16th for a separate $50 fee for both the conference and short courses.

There will be no refunds after November 16th, but substitution of another registrant is permissible.

Bound proceedings, which include handouts for all tutorials, will be provided to all attendees.

Credit Card Payment: Card Type: American Express ❑ Master Card ❑ Visa ❑ **(No other credit cards accepted)**

Card Number:_____ **Expiration Date:**_____

Card Holder Signature: _____

***On-site course registration requires advance e-mail or telephone notification so we can guarantee sufficient space and materials.**

2007 DEMING CONFERENCE ON APPLIED STATISTICS BOOK ORDER FORM

Author, *Title,* Year of Publication, Pages, ISBN Listed By Publisher	Price ($) List	Price ($) Our	# Of Copies	Total ($)
Taylor and Francis				
Carlin, Bradley and Louis, Thomas, *Bayes and Empirical Bayes Methods for Data Analysis*, 2nd Edition, 2000, ISBN: 1584881704	75	48		
Chang, Mark, *Adaptive Design Theory and Implementation Using SAS and R,* 2007, 424 pages, ISBN: 9781584889625	90	57		
Daniels, Michael and Hogan, Joseph, *Missing Data in Longitudinal Studies: Dropout, Casual Inference and Sensitivity Analysis*, 2007, 416 pages, IBSN 10: 1584886099	80	51		
Shoukiri, Mohamed and Chaudhary, Mohammad, *Analysis of Correlated Data with SAS and R*, 3rd Edition, 2007, 312 pages, IBSN 10: 1584886099	90	57		
John Wiley & Sons, Inc.				
Box, George and Draper, Norman, *Response Surfaces, Mixtures, and Ridge Analyses*, 2nd Edition, 2007, 857 pages, IBSN 978-0-470-05357-7	115	69		
Brown, Helen and Prescott, Robin, *Applied Mixed Models in Medicine*, 2nd Edition, 2006, 455 pages, IBSN 978-0-470-02356-3	130	77		
Chernick. Michael, *Bootstrap Methods: A Practitioner's Guide*, 2nd Edition, 2007, IBSN 978-0-471-75621-7	110	66		
Chevret, Sylvie, *Statistical Methods for Dose-Finding Experiments*, 2006, 334 Pages, IBSN 978-0-470-86123-3	110	66		
Fleiss, Joseph, Levin, Bruce, and Paik, Myunghee, *Statistical Methods for Rates and Proportions* 3rd Edition, 2003, 800 pages IBSN 978-0-471-526292	119	71		
Hu, Feifang and Rosenberger, William, *The Theory of Response-Adaptive Randomization in Clinical Trials*, 2006, 232 pages IBSN 978-0-471-65396-7	96	58		
Shmueli, Galit, Patel, Nitin and Bruce, Peter, *Data Mining for Business Intelligence: Concepts, Techniques, and Applications in Microsoft Office Excel with XLMiner,* 2006, 276 pages, IBSN 978-0-470-05357-7	100	60		

Total Order: $ _____

TO PLACE AN ORDER Please include completed book order form and book payment with conference registration material. Include completed book order form with conference registration material to reserve books for purchase at the conference. The conference only orders a few extra books. Thus the availability of all books on site cannot be guaranteed unless you place an order before the registration deadline.

ORDER PICK-UP Please claim your books at the conference sign-in table during conference hours between 8am Monday December 3 and noon of Wednesday December 5. Individuals attending a course, but not the conference, may pick up their books during the course. Unclaimed books will be mailed after the owners pay the postage.

QUESTIONS ABOUT THE ORDER PROCESS? Contact Wenjin Wang at wangw@wyeth.com.

TRAVEL TO THE CONFERENCE

AIR: Check both Atlantic City (ACY) and Philadelphia (PHL) to search for the best fare and connections. Adventure Trails, (609) 272-9140, gets one to the Tropicana from ACY for less than half the cost of a cab. The cheapest connection from PHL is the below referenced SEPTA, but this will take about two hours. Royal Airport Service, (888) 824-7767, is the recommended limousine from PHL, but renting a car may be cheaper (www.bnm.com). Discount airlines not on the major search engines such as Spirit, www.spiritair.com, to ACY; and AIRTRAN, www.airtran.com; America West, www.americawest.com; ATA, www.ata.com; Frontier, www.frontierairlines.com; Southwest, www.southwest.com; and USA 3000, www.usa3000airlines.com to PHL should also be considered. These airlines offer the additional advantage that they sell one-way tickets without a premium that is useful if one is using the conference as a stopover. While we don't recommend Newark Airport, there is a #67 NJ Transit bus (requiring a change at Toms River) as well as train service (with two changes) to Atlantic City. The whole trip would take about three hours as opposed to about ninety minutes if one rented a car.

RAIL: NJ Transit has relatively frequent local (14 daily trips with 6 stops) service to Philadelphia connecting with Amtrak and SEPTA at 30th Street and PATCO at Lindenwald, NJ. Free shuttle busses meet all trains and provide direct service to all casinos. For a schedule, see www.njtransit.com/pdf/rail/r0090.pdf. This schedule also shows the R1 SEPTA connections from PHL to 30th Street.

BUS: Check your local paper or call the Tropicana casino bus transportation department, 888-275-1212 # 1. There may be a casino bus trip from your local neighborhood as some of these busses travel as far as 200 miles. Most allow you to return on a different day for a charge or a space available basis. Cost of the trip will be offset by casino cash back rebates and other offers. One may take a bus to any casino, collect their coins and coupons and use a $1.50 jitney on Pacific Avenue to quickly and cheaply get to the Tropicana. www.greyhound.com/products_services/casino_nj.shtml will give you information on Greyhound's service directly to the Tropicana with a coin rebate, allowing you a four-day open return from a number of cities, e.g., Philadelphia, NYC, Baltimore and Washington.

DRIVING: To get to the Tropicana from the Garden State Parkway, NJ Turnpike or Philadelphia, take the Atlantic City Expressway. Follow the Atlantic City Expressway to Exit 2. This will take you to the Black Horse Pike, Rt. 40/322, which you will take into Atlantic City. Turn left on Arctic Avenue, the first light over the bridge. Take Arctic Avenue to Brighton Avenue. Turn right on Brighton and cross Atlantic Avenue. The entrance to the Havana Tower garage (both self-park and valet) is on your left after Atlantic Avenue. Don't park in the Tropicana's other garage, as it is tedious to get to the Havana Tower. We don't recommend valet parking, as this does not allow you easy access to your car during your stay. There is a $5 hotel guest-parking fee that permits unlimited entry and exit.

PROMOTIONS: Check your local Sunday paper for coupons. The Philadelphia Inquirer occasionally prints show and meal discount coupons both Friday and Sunday. Check www.tropicana.net to view their promotions. For other casinos, check their web sites or promotion booths to see what they have to offer.

INFO: For maps, an events schedule, casino shows and general tourist info, call the Atlantic City Convention Bureau at (888) 228-4748. View their web site at www.atlanticcitynj.com that has an option for you to request a free visitor packet as well as an opportunity to e-mail questions that are promptly answered. Consider walking to and shopping in the upscale Atlantic City Outlets at Atlantic and Michigan or the pier shops at Caesars. Remember there is no sales tax on clothes in New Jersey. Also check out the many shopping and dining discounts on Wednesday December 5th (First Wednesday)

MEALS: We suggest printing a map of the Havana Tower on www.tropicana.net/images/map.pdf. Besides giving information on how to find registration, parking, and the meeting, it gives one an idea of the available restaurants and attractions. There are eight restaurants besides those in the Havana Tower. The *Beachfront* Buffet offers reasonably priced, all-you-can-eat meals. *Pier 7* offers impressively prepared seafood, while *The Seaside Café* offers a wide variety of options 24 hours a day. *Wellington & Chan's* and *Golden Dynasty* offer their respective takes on food from the Far East, while *Il Verdi* offers gourmet Italian Cuisine. If one is in the mood for something more casual, *Hooters* is located conveniently on the first floor, adjacent to the Boardwalk. Outside of the Tropicana and along the Boardwalk are a wide variety of restaurants to suit any taste or budget, from classic seafood restaurants to *Burger King*. We will provide a continental breakfast before our morning session as well as an afternoon refreshment break at 2:30 PM. Also, there will be an optional subsidized Speaker Dinner on Monday. There will be a one-hour reception on Sunday evening with cold drinks, snacks and a cash bar to allow you to register and meet with your fellow attendees.