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

Sponsored by
AMERICAN SOCIETY FOR QUALITY
NY/NJ Metropolitan Section ~ ~ Statistics Division
AMERICAN STATISTICAL ASSOCIATION
Biopharmaceutical Section

December 8 – December 10, 2008: Three-Day Conference
Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ

Short Courses: – December 11-12, 2008

1 Mixed Models for Clustered and Longitudinal Data by Professor Donald Hedeker, University of Illinois at Chicago

2. Statistical Meta-Analysis with Applications by Professor Bimal Kumar Sinha, University of Maryland

A $4,000 college scholarship will be awarded to an undergraduate spouse, child, stepchild, or grandchild of a registrant

REGISTRATION WILL BE ON THE FOURTH FLOOR OF THE HAVANA TOWER.
It will start at 6:00 pm on Sunday December 7th 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.
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

AMERICAN SOCIETY FOR QUALITY

Westfield, NJ
Permit Number 9

The conference will use the meeting facilities in the Tropicana's 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. It has world-class dining, non-stop entertainment, a dazzling array of upscale shops and experiences and an 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

Keaven Anderson has been the Executive Director of late-stage statistics for Merck Research Laboratories since December 2003. Previously, Dr. Anderson had worked for Centocor for 13 years and the Framingham Heart Study for 6 years. He was a post-doctoral fellow at the Harvard School of Public Health following receipt of his Ph.D. in Mathematical Statistics from Stanford University and his Bachelor of Science in Statistics from Iowa State University. His interests have included oncology, cardiovascular disease epidemiology and clinical trials, survival analysis modeling and clinical trial design, including group sequential design and adaptive design.

Thomas E Bradstreet is Director, Scientific Staff, Experimental Medicine Statistics at Merck Research Labs. Dr. Bradstreet's statistical and research areas of interest include distributions of order k, permutation tests, combinatorics, graphics, statistical education, and the Behrens-Fisher problem. He has published numerous papers and book reviews. Dr. Bradstreet has been an associate editor for the *Journal of the American Statistical Association* (Reviews), *The American Statistician* (Reviews), and the *Biopharmaceutical Report*. Dr. Bradstreet received "best paper" awards for statistics and SAS software presentations and / or manuscripts.

Brad Carlin is Mayo Professor in 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 110 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/

Shein-Chung Chow is a Professor at the Department of Biostatistics and Bioinformatics, Duke University School of Medicine, Durham, NC. Dr. Chow is the Editor-in-Chief of the Biostatistics Book Series at Chapman and Hall. He is a Fellow of the American Statistical Association and an elected member of the International Statistical Institute. He was the recipient of the DIA Outstanding Service Award, ICSA Extraordinary Achievement Award, and Chapter Service Recognition Award of the ASA (1998).

Richard Cook is Professor of Statistics at the University of Waterloo and Canada Research Chair in Statistical Methods for Health Research. He received his PhD in 1993. He has published extensively in the areas of statistical methodology, clinical trials, medicine and public health on the statistical analysis of recurrent events and in journals such as Biometrics and Statistics in Medicine. He has consulted widely with pharmaceutical companies and contributed to the design and analysis of numerous clinical trials.

Dennis Cosmatos has been involved in building, developing and leading four dedicated statistical Groups in four different organizations, covering all therapeutics areas and Research and Development activities from Discovery to Pre-Clinical safety and efficacy to Phase I-III clinical studies. He has experience in supporting genomic, proteomic and gene therapy studies. He recently led a Biostatistics Group that supported clinical pharmacology, biomarker development and Translational Medicine activities at Wyeth.

Alan Hartford is Associate Director, Scientific Staff, Clinical Pharmacology Statistics at Merck Research Labs. Dr. Hartford leads a group of statisticians working collaboratively with pharmacokineticists, clinicians, and mathematicians performing pharmacokinetic/pharmacodynamic modeling in support of drug development at Merck. Dr. Hartford has publications on computational methods for nonlinear mixed effects models and on performing mechanistic modeling on clinical trial data.

David W. Hosmer is Professor of Biostatistics (Emeritus) in the Department of Public Health at the University of Massachusetts and is an Adjunct Professor of Statistics in the Department of Mathematics and Statistics at the University of Vermont. He is a Fellow of the American Statistical Association and is a coauthor with Stanley Lemeshow of the text *Applied Logistic Regression*.

H.M. James Hung is Director of Division of Biometrics I, CDER, FDA. This provides services for 3 medical divisions of drug products (cardiovascular and renal, neurology, psychiatry). In his 19-year FDA tenure, he reviewed many large mortality/morbidity trials in cardiovascular-renal areas. He has 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.

Jeanne Kowalski is Assistant Professor at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins. In addition to Modern Applied U-Statistics, she is currently co-editing a book series entitled Applied Bioinformatics and Biostatistics in Cancer Research for Springer Science. Dr. Kowalski's primary research interest is in nonparametric modeling of high-dimensional data, with specific application to genomic association studies of cancer.

Edward Lakatos, Ph. D. joined NIH in 1978, where he was the project statistician on many large cardiovascular trials. This led to his Markov approach for designing complex survival trials, considered the gold standard for the logrank statistic. In 1992 he joined the Pharmaceutical Industry, where he was instrumental in the submission of many NDA's. He formed BiostatHaven Inc. in 2002 and was awarded an NIH grant to develop STOPP™, to provide software for his statistical contributions. He is an ASA Fellow.

Jerry Lawless is a Professor of Statistics at the University of Waterloo. He received his PhD in 1969 and has published extensively on statistical methods for survival and event history data, applications in medicine, public health, and reliability. He is the author of the book Statistical Models and Methods for Lifetime Data (2nd Wiley edition, 2003). He has consulted widely in government, industry and public health and held the GM-NSERC Industrial Research Chair in Quality and Productivity from 1994 to 2004.

Min Lin is Assistant Professor of Biostatistics and Bioinformatics at Duke University. Dr. Lin received her Ph.D. in statistics at the University of Florida in 2005. Her research interest centers on statistical modeling of the associations between genetic polymorphisms and biological or clinical phenotypes. She is particularly interested in the identification of genetic variants that regulate pharmacodynamic drug responses.

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 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.

Xin Tu is Professor of Biostatistics and Psychiatry and Director of the Psychiatric Statistics Division within the Department of Biostatistics and Computational Biology at the University of Rochester. In addition to Modern Applied U-Statistics, he is currently co-editing a volume entitled Modern Clinical Trial Analysis for Springer Science and co writing a book entitled Applied Categorical Data Analysis.

Sue-Jane Wang is Associate Director in the Office of Biostatistics, Office of Translational Sciences, CDER, FDA. Dr. Wang's research interest and publications in recent years have been focusing on adaptive/flexible clinical trial designs, noninferiority active controlled trials, pharmacogenomic/ pharmacogenetic adaptive trials with use of genomic biomarker classifier. Her collaborative research has resulted in more than 60 professional publications. She is an Editor in Chief of Pharmaceutical Statistics Journal.

Rongling Wu trained in genetics at the University of Washington, where he received his Ph.D. in 1995. He is now intrigued by the development of statistical models for genetic and genomic research in plants, animals and humans. He brings together cutting-edge research across a broad range of subjects, including genetics, developmental

Monday December 8, 2008
8:30 – 11:30 AM

Session A
Roles of Adaptive Designs in Drug Development
Speakers: Drs. H. M. James Hung and Sue-Jane Wang
U.S. Food and Drug Administration
Moderator: Ivan Chan

There have been many experiences indicating insufficiency of conventional non-adaptive fixed designs, in particular, if the trial design is expected to answer many study questions and subsequently the level of difficulty in conducting the trial rises significantly. Methods have been proposed in the literature for adaptation of clinical trial designs for evaluation of an experimental treatment. The recent advances in adaptive design methodology have been made, ranging widely from a new look of sample size re-estimation to a mid-term change of statistical decision tree, such as alpha allocation. This tutorial will give a brief overview of the statistical methodologies, some major advances, and present the scenarios where some types of adaptation may be worthy of and needs further exploration. Topics to be covered include: learn versus confirm paradigm, sample size reestimation, adaptive design versus adaptive strategy, and their roles in drug development program. The issues on both the ability of adaptive designs to draw a valid statistical inference and logistic aspects that will have a great impact on quality of trial conduct will be studied in detail. A few case studies derived from regulatory applications will be discussed. The potential utility and pitfalls of adaptive designs will be explored in the early phase and late phase of drug development.

Session B📖
Statistics in Translational Medicine
Speakers: Dr. Dennis Cosmatos
Prof. Shein-Chung Chow, Duke University School of Medicine
Moderator: Xiaoming Li

This tutorial will focus on strategies and statistical considerations for assessment of translation in language (e.g., translation of case report forms in multinational clinical trials), information (e.g., translation of basic discovery to clinic) and technology (e.g., translation of Chinese diagnostic techniques to well established clinical study endpoints) in pharmaceutical/clinical research and development. However, most of our efforts will be directed to statistical considerations for translation in information. Pizzo (2006) defines translational medicine as "bench-to-bedside" research wherein a basic laboratory discovery becomes applicable to the diagnosis, treatment or prevention of a specific disease and is brought forth by either a physician-scientist who works at the interface between the research laboratory and patient care or by a team of basic and clinical science investigators. Statistics plays an important role in translational medicine to ensure that the translational process is accurate and reliable with certain statistical assurance. For this purpose, statistical criteria for assessment of one-way and two-way translation are proposed. Under a well-established and validated translational model, statistical tests for one-way and two-way translation are derived. Strategies for selection of clinical study endpoints (e.g., absolute changes, relative changes, or responder defined either based on absolute change or relative change, etc) are reviewed. Statistical inferences for lost in translation and for the applicability of an animal model to a human model are also discussed.

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

1:00 - 4:00 PM

Session C
Sample Size Reestimation and Group Sequential Designs In Clinical Trials
Speaker: Dr. Keaven M. Anderson, Merck Research
Moderator: Ivan Chan

As a clinical trial begins, there is often uncertainty about key assumptions required to select an appropriate sample size. Two ways to deal with this issue are 1) plan the sample size conservatively and use interim analyses to stop the trial early if emerging results are strong (group sequential design), and 2) re-estimating (normally, this means increasing) the sample size based on interim results (sample size re-estimation, or SSR). This session is designed to give the attendee introductory, practical advice in applying various group sequential and SSR techniques. A single example will be used to each of the methods discussed. Group sequential design topics: 1) Basic principles and theory, including types of endpoints that may be studied, 2) When are group sequential designs useful? 3) Strategies for setting efficacy and futility bounds, including discussion of conditional power and error spending, 4) Spending functions, 5) Non-inferiority trials, 6) Estimation and confidence intervals, 7) Software (free and commercial).

SSR topics include practical advice on: 1) Blinded SSR, and 2) Unblinded SSR. Blinded SSR involves estimating a nuisance parameter without unblinding data and is quite useful in appropriately sizing a trial in some cases – but not others. Unblinded SSR uses the emerging treatment effect to aid in SSR. This is more controversial from a regulatory perspective, which has practical implications that will be discussed during the session.

Session D📖
Statistical and Computational Pharmacogenomics
Prof. Rongling Wu, University of Florida
Professor Min Lin, Duke University
Moderator: Jackie Kennedy

The materialization of an emerging idea for personalized medicine – purported to apply the right drug in the right dose for the right person at the right time – relies critically on our ability to identify all relevant genetic variants in each patient and interpret this information in a clinically meaningful manner. With the availability of growing amounts of single nucleotide polymorphism (SNP) data, there is a pressing need for sophisticated statistical models and methods that can detect specific DNA sequence variants responsible for drug response. This tutorial will provide an overview of genetic designs and statistical methods for associating SNP genotypes or haplotypes with complex traits. Because drug response can be better described as curves, the emphasis will be on a new statistical strategy, called functional mapping, derived to compute genes and genomes for a dynamic trait and study the interplay of genetic actions and the pattern of biological processes. This tutorial includes three parts:

(1) Basic genetic concepts and principles for genetic mapping,
(2) General statistical framework for functional mapping of longitudinal traits,
(3) Statistical and computational issues related to mapping multiple aspects of drug response, such as pharmacokinetics/ pharmacodynamics, and drug efficacy/drug toxicity.

A number of examples will be demonstrated to help the students understand the key concepts and methods for pharmacogenetic and pharmacogenomics studies. The computer code for the statistical methods discussed will be available from our web page.

Tuesday December 9, 2008
8:30 – 11:30 AM

Session E📖

Introduction to Regression Modeling of Time to Event Data

Speaker: Professor David W. Hosmer

Biostatistics Program, University of Massachusetts

Moderator: Walter R. Young

This tutorial will provide participants with an introduction to regression modeling of time to event or survival data. Emphasis is placed on using the proportional hazards model with right-censored data. The tutorial emphasizes methods and their application. Covered topics include: regression model formulation, interpretation of model parameters, model building strategies, testing model assumptions, assessing model fit, presenting the results of a fitted model and, if time permits, time-varying covariates. Methods are all illustrated with applications to real data. The tutorial is organized as follows:

1) Introduction to Time to Event Data, Review of the Kaplan-Meier Estimator, Estimators of Quantiles, the Log-Rank & other tests.
2) Regression Models for Survival Data: Introduction, Semi-Parametric Regression Models, Fitting the Proportional Hazards Regression Model, Estimating the Survival Function of the Proportional Hazards Regression Model.
3) Interpretation of a Fitted Proportional Hazards Regression Model: Introduction, Nominal Scale Covariate, Continuous Scale Covariate, Covariate Adjusted Survival Function.
4) Model Development: Introduction, Selection of Covariates, An example

Other possible topics to be discussed, time permitting, include: Methods for Assessing the Proportional Hazards Assumption, Identification of Influential and Poorly Fit Subjects, Overall Goodness-of-Fit Tests and Measures, Interpretation and Presentation of the Final Model.

Session F📖

Modern Applied U-Statistics

Speakers: Professor Jeanne Kowalski, Johns Hopkins
Professor Xin Tu, University of Rochester

Moderator: Jackie Kennedy

U-statistics have found novel applications in many areas of research in biomedical and behavioral and social sciences. Unlike regression analysis, U-statistics are designed to model higher order moments, which is particularly useful for addressing complex modeling problems found in the areas of genetic, behavior and psychosocial research. The book introduces the theory of U-statistics and its modern applications by in-depth examples that cover a wide spectrum of models in biomedical and psychosocial research. The book presents U-statistics as an integrated body of regression-like models, with particular focus on longitudinal data analysis. This book fills a critical void in this vital research sector. By integrating U-statistics models with regression analyses, the book unifies the two classic dueling paradigms---the U-statistics based non-parametric analysis and model-based regression analysis---to present the theory and application of U-statistics in an unprecedented broad and comprehensive scope. The aim of this tutorial is to provide an understanding of the types of applications and models that are particularly amenable to treatment by U-statistics and U-statistics-based, regression-like functional response models (FRM). Core concepts will be introduced for the use of U-statistics and FRM. Applications for modeling longitudinal study data, and address inference using a class of U-statistics based weighted generalized estimating equations will be discussed. Several applications for which U-statistics and FRM based models are used in problems in biomedical and psychosocial research will be given.

Tuesday Lunch (On Your Own) 11:30 AM - 1:00 PM
1:00 - 4:00 PM

Session G

Pharmacokinetic/Pharmacodynamic Modeling: Concepts and Methods

Speaker: Dr Alan H Hartford, Merck Research Lab.

Moderator: Kalyan Ghosh

PK/PD modeling for drug development using nonlinear mixed-effects models has been performed for many years. Historically, pharmacokineticists usually perform this modeling and terminology has made it challenging for statisticians to contribute to the scientific discourse. However, the pharmacokineticists in this field have been warmly welcoming more statisticians to participate in expanding this field of knowledge and practice. In an effort to make this field more accessible to statisticians, this tutorial introduces concepts and methods for using nonlinear mixed-effects models for examining relationships between pharmacokinetic and pharmacodynamic endpoints, bridging the differences in terminology. Included will be the following topics: endpoints of interest, purpose of PK/PD modeling for drug development, construction of the mechanistic structural models via systems of differential equations, construction of the stochastic models, distributional and other assumptions, study design and sampling design concerns in relation to data set creation, model selection, diagnostics, simulations, and current software appropriate for PK/PD modeling. Examples will be provided for hands-on instruction using the R language. A basic understanding of maximum likelihood estimation, regression, and differential equations is assumed but no prior knowledge of nonlinear regression is required.

Session H

Optimizing Group-Sequential Designs Focusing on Adaptability with STOPP™ Software

Speaker: Edward Lakatos, BiostatHaven Inc.

Moderator: Alfred H. Balch

This tutorial focuses on trials with interim analyses. Recently, there has been considerable discussion of the merits of group sequential versus adaptive methods. While the competing merits of the two approaches have been debated frequently, this presentation will spend little time on this. Rather, we will concentrate on how to optimize the design and interim analysis strategy for survival trials. Our approach departs from the standard. First, we do not use the typical measures of optimality, as real-world considerations render these less meaningful. Our approach is to carefully examine the literature relevant to the therapeutic area and the proposed trial, and then design the interim analysis strategy around the findings of this review. The approach relies heavily on the Markov model for modeling trials with nonlinear risk functions. The tutorial will first present basic methods for designing group sequential survival trials with nonlinear risk functions, with emphasis on the Markov model. We will then show how to extract crucial survival information from prior trials, and then use this to build group sequential designs satisfying various optimality conditions. We will also show how to build a group sequential design for survival trials having nonlinear risk functions that provides some important adaptive characteristics. Throughout the presentation, STOPP™ software will be used to demonstrate how these designs are optimized. Central to much of the adaptive design literature, is the computation of conditional power. The impact of nonlinear risk functions on conditional power will also be discussed.

Wednesday December 10, 2008
8:30 – 11:30 AM

Session I
Effective Communication Through Graphics
Speaker: Thomas E. Bradstreet, Ph.D.
Experimental Medicine Statistics, Merck Research
Moderator: Kalyan Ghosh

Effective communication through graphics is a prerequisite skill for any professional or student statistician (or non statistician) practicing in industry, government, or academia who is involved either with the analysis and/or visual display of data, or is a consumer of data based information. The effective communication dimension of graphics is often overlooked in the formal training of many disciplines. To highlight its importance, we must consider the price to be paid for misrepresentations, misinterpretations, and miscommunications due to poorly designed and constructed graphs which result in poor scientific, business, and public policy decisions. Visualization, interpretation, and decision making activities can occur at any point along the information continuum from exploration, discovery, and insight during data analysis, to subsequent inference and decisions, to final presentation with clarity and efficiency. Participants will gain an awareness of, and exposure to, the principles of perception, design, and construction of graphic displays of both quantitative and qualitative information. With a critical eye, participants will be able to construct, revise, and interpret graphical displays based upon a set of guidelines that are general and flexible enough to be applied in most data analysis and final presentation situations. The guidelines will be demonstrated with specific examples of what to do and what not to do, based upon real data sets, graphs from peer reviewed journals and reference books, and the author's own experiences. The tutorial is designed to be interactive with lots of collaborative discussions.

Session J📖
Statistical Methods for the Analysis of Recurrent Event Data
Speakers: Professors Richard Cook and Jerry Lawless
University of Waterloo
Moderator: Wenjin Wang

The analysis of recurrent events is often based on models for event counts, gap times, or event intensity functions. This tutorial considers each of these frameworks. The mean function of a recurrent event process gives the expected number of events as a function of time, and the derivative of the mean function gives the rate of event occurrence. These functions are often of central importance when event counts are the focus. Poisson and mixed Poisson process models are most conveniently used for the estimation of mean and rate functions when full models are required, but robust marginal methods are also available based on estimating functions. These methods do not require the assumption of any specific model. It turns out that software for the Cox survival model can deal with popular models for rate and mean functions. The analysis of gap times can also often be carried out by adapting models and software for survival analysis, and are most appealing when interest lies in estimating the distribution of times between events and assessing covariates associated with these times. Event intensity functions provide the most general approach. They characterize the way in which the risk of events depends on the previous number and times of events so intensity-based analyses can offer useful insight into the factors driving event occurrence. The merits, interpretations, and methods of inference will be discussed for these three frameworks for modeling and analysis. Methodology presented will be illustrated on examples taken from health research and reliability and analyses will be based on S-PLUS/R and SAS. Sample code will be provided.

Wednesday Lunch (On Your Own) 11:30 AM - 1:00 PM
1:00 - 4:00 PM

Session K📖
Intermediate Bayesian Data Analysis Using WinBUGS & BRugs
Speakers: Professor Brad Carlin, University of Minnesota
Professor Tanzy Love, Carnegie Mellon University
Moderator: Ivan Chan

Most statisticians and health policy researchers have been exposed to Bayesian methods, and have some idea about the hierarchical modeling and other settings in which they offer substantial benefits. But actually obtaining these benefits remains out of reach for many, due to a lack of experience with modern Bayesian software in the analysis of real data. In this workshop, we will offer a hands-on opportunity to explore the use of WinBUGS, the leading Bayesian software package, in a variety of important models, with special attention paid to clinical trial design and analysis, and to joint models for longitudinal measurements and survival data. Basic elements such as model building, MCMC convergence diagnosis and acceleration, and posterior plotting and summarization will be mentioned, as well as (time permitting) important data-analytic procedures such as residual analysis, model adequacy (through Bayesian p-values and CPO statistics), variable selection, and model choice (through posterior probabilities and DIC statistics). In addition to WinBUGS, we will also provide a brief introduction to BRugs, the new version of BUGS available directly within the popular R package, which enables simultaneous use of the features of both languages. Students should bring their own laptop computers to the session, with the latest versions of WinBUGS and R already installed on their computers. Both programs are freely available from links at www.biostat.umn.edu/~brad/

Session L📖
Mixed Models For Longitudinal Ordinal And Nominal Data
Speaker: Prof Donald Hedeker, University of Illinois @ Chicago
Moderator: Alfred H. Balch

Ordinal and nominal outcomes are common in many areas of research. Additionally, it can be the case that these outcomes are repeatedly measured from individuals. This tutorial will focus on generalizations of the logistic regression model for categorical longitudinal data, within a mixed model framework. Specifically, the following models will be described and compared: mixed-effects logistic regression for nominal outcomes, and mixed-effects proportional odds and non-proportional odds models for ordinal outcomes. The latter models are useful because the proportional odds assumption of equal covariate effects across the cumulative logits of the model is often unreasonable. Instead, allowing the covariates to have varying influences across the cumulative logits of the ordinal responses provides a very flexible approach to the modeling of ordinal outcomes. To illustrate and compare model features, analyses will be presented of a dataset where psychiatric homeless subjects were repeatedly assessed in terms of their housing situation (classified as either independent, community, or variable housing). Treatment of these repeated housing status classifications, as ordinal and nominal outcomes will be compared. Use of SAS PROC NLMIXED for these models will be described and illustrated.

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

TWO SIMULTANEOUS SHORT COURSES
THURSDAY AND FRIDAY, DECEMBER 11-12, 2008
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 for Clustered and Longitudinal Data

Instructor: Prof. Donald Hedeker, University of Illinois at Chicago
Moderator: Alfred H. Balch

Text: Longitudinal Data Analysis, John Wiley, 2006

Day 1 of the course will cover:

- Analysis of clustered 2- and 3-level continuous data
- Multilevel representation of the mixed model
- Analysis of longitudinal continuous data
- Time-varying covariates: within- and between-subjects effects

Day 2 of the course will cover

- Analysis of longitudinal dichotomous data
- Subject-specific versus Population-averaged effects
- Missing data in longitudinal studies
- Pattern-mixture and shared parameter models

Mixed models (a.k.a. multilevel or hierarchical linear models) are increasingly used for analysis of clustered and longitudinal data. In this short course, attendees will learn about the use of mixed models for analysis of both clustered and longitudinal data, considering both continuous and dichotomous outcomes. The focus will be on application of these models, with direct application illustrated using standard statistical software (i.e., SAS). For clustered data, the basic mixed-effects regression model will be introduced and described, including its multilevel representation and connections to ordinary regression analysis. For longitudinal data, several topics will be described including the use of polynomials for expressing change across time, treatment of time-invariant and time-varying covariates, and modeling of the variance-covariance structure of the repeated measures. Some aspects of model estimation and inference will be reviewed. For dichotomous longitudinal data, mixed logistic regression models will be presented and described. Attention will be paid to the "subject-specific" interpretation of the parameters in these models, as well as techniques for deriving "population averaged" estimates. Finally, since mixed models allow for incomplete data across time, it is important to consider the topic of missing data in longitudinal data analysis. For this, the basic missing data mechanisms will be described, in particular the "missing at random" (MAR) assumption, which is made by mixed models under maximum likelihood estimation. Approaches that can go further, and don't necessarily assume MAR, are through the use of pattern mixture and selection models. Applications will be described of mixed pattern mixture and selection models, including illustrations of how to estimate such models using standard software.

Donald Hedeker is Professor of Biostatistics in the School of Public Health at the University of Illinois at Chicago. He has published over 100 research articles and one book, and is the primary author of several freeware statistical programs for mixed model analysis. In 2000, he was named a Fellow of the American Statistical Association. He currently serves as an Associate Editor for *Statistics in Medicine* and *Journal of Statistical Software*.

Statistical Meta-Analysis with Applications

Instructor: Professor Bimal Kumar Sinha, University of Maryland
Assisted by Martin Klein, Graduate Student, UMBC
Moderator: Xiaoming Li

Text: Statistical Meta-Analysis with Applications, John Wiley, 2008

Day 1 of the course will cover:

- Introduction
- Effect Size
- Combination of Tests
- Combination of Estimates
- Common Mean
- Tests of Homogeneity
- One-Way Random Effects Model

Day 2 of the course will cover

- Publication Bias
- Vote Counting Procedures
- Combination of Polls
- Analysis of Binary Data
- Computational Aspects
- Data Sets

Statistical meta-analysis, a.k.a. data-integration, data synthesis, or evidence pooling, deals with performing analysis of analyses! Given the results of some primary studies, all sharing a common goal, we will discuss various statistical methods to combine the evidence from component studies to arrive at a consensus. Since the nature of primary studies can be varied and widely different, a proper statistical meta-analysis would require a host of different techniques, and our goal in this workshop is to present a wealth of such methods. Some computational aspects using SAS and R will also be discussed.

Bimal Sinha is Presidential Research Professor in Statistics and the Founder of the Statistics Graduate Program at University of Maryland Baltimore County. His research activities span over several topics in theoretical and applied statistics: multivariate analysis, linear models, ranked set sampling, environmental statistics, meta-analysis, decision theory, etc. He has coauthored four books (John Wiley, Springer, Academic) and published over 100 research articles. He is a Fellow of the American Statistical Association and the Institute of Mathematical Statistics, and an elected member of the International Statistical Institute. He currently serves on the editorial board of several international statistics journals, and a past Editor of *Calcutta Statistical Association Bulletin*. For more information on Professor Sinha, please visit www.math.umbc.edu/people/sinha.htm.

Martin Klein is a PhD student in statistics at UMBC under Professor Sinha's supervision, and his doctoral dissertation is on statistical analysis based on PB/PK models. He is expected to graduate in May 2009.

Committee

Chairman & Program
Walter R. Young*
16 Harrow Circle
Wayne, PA 19087
(610) 989-1622
demingchair@gmail.com

Registrar
Eric Grossman
New York City Transit
10 Andover Drive
Deer Park, NY 11729
(516) 909-5330
Fax # (631) 254-6623
demreg@optonline.net

Treasurer
Joseph G. Borden
3246 Pheasant Trail
Mims, FL 32754
(321) 626-4728

Arrangements
Satish Laroia
Larson Associates
33 Aspen Circle
Edison, NJ 08820
(973) 812-9033
Fax # (732) 549-7487
satishlaroia@aol.com

Transactions
Edward Warner
Schering-Plough Corp.
Bldg S-3-2
556 Morris Avenue
Summit, NJ 07901
(908) 473-6988
Fax # (908) 473-3182
ed.warner@spcorp.com

Program Committee

Bibliolater & Web Master
Dr. Wenjin Wang
Wyeth Research
P.O. Box 42528
Philadelphia, PA 19101
(484) 865-2201
Fax # 484-865-0072
wangw@wyeth.com

Dr. Alfred H. Balch
Myriad Pharmaceuticals
320 Wakara Way
Salt Lake City, Utah 84108
(801) 505-5119
fredbalch@juno.com

Dr. Ivan Siu Fung Chan
Merck Research Labs
Mail Stop: UG1CD-38
P.O. Box 1000
North Wales, PA 19454
(267) 305-7967
Fax # 267-305-6538
ivan_chan@merck.com

Dr. Kalyan Ghosh
Vislation
640 Lee Road
Chesterbrook, PA 19087
(610) 992-9834
kalyan.ghosh@vislation.com

Jacqueline Kennedy
P. O. Box 388
Fulton, MD 20759
(215) 815-6067
jackiekennedy11548@comcast.net

Dr. Xiaoming Li
Merck Research Laboratories
UG1CD-44
North Wales, PA 19454
(267) 305-1347
Fax # (267) 305-6538
xiaoming_li@merck.com

***Walter R. Young has chaired the Deming conference for thirty-nine 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 7th, 7:30 AM December 8th through December 10th and 8 AM on December 11th. Transmit payments and mail registration to Mr. Eric Grossman, New York City Transit, 10 Andover Drive, 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 ❑ C ❑D ❑ E ❑ F ❑ G ❑ H ❑ I ❑ J ❑ K ❑ L ❑**

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 for Clustered and Longitudinal Data**
❑ **Statistical Meta-Analysis with Applications**

Book Order Total (see reverse page) _____

Havana Tower Rate: $ 94.00 (Plus 14% Tax & $ 5 Occupancy Fee & $1 Phone = $113.16) 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 Rate

Tropicana Room Reservation (One Night Deposit of $113.16) 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 21st for a separate $50 fee for both the conference and short courses.

There will be no refunds after November 21st 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: _____

Book Order Form
2008 DEMING CONFERENCE ON APPLIED STATISTICS

Author, *Title,* Year of Publication, Pages, ISBN Listed By Publisher	Price ($) List	Price ($) Our	# Of Copies	Total ($)
Taylor and Francis				
Carlin, Bradley P. and Louis, Thomas A., *Bayesian Methods for Data Analysis, 3rd* ed., 2008, 552 p., ISBN 978-1-584-88697-6	70	45		
Cosmatos, Dennis and Chow, Shein-Chung, *Translational Medicine – Strategies and Statistical Methods*, 2008, 416 p., IBSN 1584888725	90	57		
Wu, Rongling and Lin, Min *Statistical and Computational Pharmacogenomics*, 2008, 256 p., IBSN 978-1-584-88828-4	80	51		
Springer				
Cook, Richard and Lawless, Jerry, *The Statistical Analysis of Recurrent Events*, 2007, 404 p., IBSN 978-0-387-68909-0	85	54		
John Wiley & Sons, Inc.				
Hedeker, Donald and Gibbons, Robert, *Longitudinal Data Analysis*, 2006, 360 p., ISBN: 0-471-42027-1	117	70		
Hosmer, D, Lemeshow, S, and May, S, *Applied Survival Analysis: Regression Modeling of Time-to-Event Data*, 2nd Ed., 2008, 416 p., IBSN 978-0-471-75499-2	110	63		
Kowalski, Jeanne and Tu, Xin, *Modern Applied U-Statistics*, 2007, 378 p., IBSN 978-0-471-68227-1	106	66		
Sinha, Bimal, Hartung, Joachim, and Knapp, Guido, *Statistical Meta-Analysis with Applications*, 2008, 288 p., IBSN 978-0-470-29089-7	95	57		

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 pick up at the conference. The conference only orders a few extra books. Thus the availability of books on site cannot be guaranteed unless you place an order in advance.

ORDER PICK-UP Please claim your books at the conference sign-in table during conference hours between 6pm Sunday December 7 and noon of Wednesday December 10. 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. **For any questions on ordering books, 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. There is also a slow, cheap NJ Transit service requiring a change in Pleasantville. 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; 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. Free shuttle busses meet all trains and provide direct service to the Tropicana. www.njtransit.com/pdf/rail/current/r0090.pdf has a schedule that 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 since 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 get to the Tropicana. www.greyhound.com/home/en/DealsAndDiscounts/LuckyStreakNJ.aspx contains information on Greyhound's service directly to the Tropicana with a coin rebate, and 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 doesn't permit easy access to your car during your stay. There is a $5 hotel guest-parking fee that permits unlimited entry and exit during your stay.

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 visit the Atlantic City Convention Bureau website 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.

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 *Fiesta* Buffet offers reasonably priced, all-you-can-eat meals. *The Seaside Café* offers a wide variety of options 24 hours a day. *Wellington* and *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 sessions as well as afternoon refreshment breaks 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.

Walter Young Scholarship: The ASQ Metropolitan Section will award one $4,000 college scholarship to an undergraduate spouse, child, stepchild, or grandchild of a registrant. The application and complete rules are on the conference website and background information is on www.metro-asq.org. The application must be submitted after the conference and before April 1, 2009. The award will be announced and paid directly to the applicant on May 15, 2009. The applicant must be accepted or matriculated at an accredited college or university in the United States and have at least a 2.75 grade point average. The winner and three members of his immediate family will be invited to an awards dinner in June 2009 but attendance is not mandatory and travel expenses to the dinner will not be paid. The Scholarship Committee,