



# PROGRAMME OF THE SIXTY-FIRST ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS

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

December 5 – December 7, 2005: Three-Day Conference  
Tropicana Casino and Resort, Atlantic City, NJ

## Short Courses: – December 8-9, 2005

1. An Introduction to Generalized Linear Mixed Models by Charles E. McCulloch (UCSF)
2. Bioequivalence and Statistics in Clinical Pharmacology by Scott Patterson (GlaxoSmithKline)  
Professor Byron Jones (Pfizer)

**REGISTRATION WILL BE ON THE FOURTH FLOOR OF THE HAVANA TOWER.**

**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](http://www.demingconference.com)

for further details.

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NY/NJ Metropolitan Section  
American Society for Quality  
**ASQ**  
Walter R. Young, Chair  
16 HAITOW Circle  
Wayne, PA 19087



- The conference will use the meeting facilities in the 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, \$4 for each day that you enter.
  - There is a guest check in desk on the third floor of the Havana Tower and all meeting facilities are on the fourth floor.
  - The casino is in a separate building connected by a bridge over Pacific Avenue.
  - The Tropicana is the largest hotel in the state of New Jersey, with elegant public areas with exclusive retail shops and fine dining.
  - Located on the beach with a fully equipped fitness facility (free for conference registrants) and a heated indoor pool.
  - A complimentary Diamond Club Card can offer rewards based on your play. It may also offer dining and show discounts.
  - This is the conference's diamond anniversary. In honor of the Diamond Club, hotel registrants will receive a "Tropicana Gift"
  - Go to [www.tropicana.net/index2.htm](http://www.tropicana.net/index2.htm) for a complete hotel and Havana Tower description and shows scheduled in December.
- 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.

## 61<sup>st</sup> ANNUAL DEMING CONFERENCE ON APPLIED STATISTICS ROOM RESERVATION FORM

**December 5-9, 2005**

**Havana Tower Rate: \$ 91.00 (Plus 13% Tax & \$ 5 Occupancy Fee & \$1 Phone = \$108.83) Per Room/Night  
Cancellation Policy - 48 hours prior to arrival**

<b>Name:</b> _____		
<b>Company:</b> _____		
<b>Address:</b> _____		
<b>City:</b> _____	<b>State:</b> _____	<b>Zip:</b> _____
<b>Home Phone:</b> _____	<b>Business Phone:</b> _____	
<b>Arrival:</b> _____	<b>Departure:</b> _____	
	(Day/Date)	(Day/Date)
Please Reserve _____ Rooms (ALL Rooms are Double/Single Occupancy)		
Check In: 3:00pm		Check Out: 12:00pm

**Reservations received after November 18, 2005 will be accepted on a space available basis only.**

**A deposit equal to one night's room, tax and occupancy fee is required to guarantee your reservation.**

**Credit Card, Personal Check or Money Order may be used for payment.**

<b><u>To Guarantee Reservation with Credit Card:</u></b>	
<b>AMX:</b> ___	<b>VISA:</b> ___
<b>MASTERCARD:</b> ___	<b>DISCOVER:</b> ___
<b>Expiration Date:</b> _____	
<b>Credit Card Number:</b> _____	<b>Signature</b> _____

Reservation requests must be faxed directly to the Tropicana at (609) 340-4007 or mailed to:

**TROPICANA CASINO AND RESORT  
ATTN: Pamela A. James, CMP, Hotel Sales  
Brighton and The Boardwalk  
Atlantic City, NJ 08401-6390**

Please mention Group code: (HDEMING)

**Session A**

**Creating More Effective Graphs** 

**Speaker: Naomi B. Robbins**

**NBR**

**Moderator: Walter R. Young**

The speaker's text describes how to draw clear, concise, accurate graphs that are easier to understand than many of the graphs one sees today. It also helps readers of graphs to read more critically and analytically so that they are not misled if they see graphs that are not properly drawn. The session begins by showing the limitations of many common graphical constructions. It continues by ranking elementary graphical perception tasks to identify those that we do the best; demonstrating newer, more effective graphical forms developed on the basis of the ranking; providing general principles for creating effective graphs; commenting on software packages that produce graphs; comparing the same data using different graph forms so the audience can see how readability depends on the graphical construction used; and discussing trellis displays (a framework for the visualization of multivariate data) and other innovative methods for presenting more than two variables. Since scales (the rulers along which we graph the data) have a profound effect on our interpretation of graphs, the section on general principles contains a detailed discussion of scales including whether zero needs to be included, when logarithmic scales improve clarity, breaks in scales and how should they be used, and informative and deceptive double axes. The session emphasizes common mistakes users of software such as Excel often make that produce confusing or even misleading graphs and how to avoid these mistakes. No statistical background is required.

**Session B**

**Multiple Comparisons And Multiple Endpoints In Clinical Trials** 

**Speaker: Alex Dmitrienko, Ph.D.**

**Eli Lilly and Company**

**Moderator: William Wubao Wang**

This session will focus on statistical strategies for handling multiplicity issues arising in clinical trials. It will cover basic single-step multiple tests and more advanced closed, fixed-sequence and resampling-based multiple testing procedures:

1. Benefits and limitations of popular single-step tests (e.g., Bonferroni and Sidak tests).
2. Multiple testing procedures derived using the powerful closed testing principle, including widely used stepwise tests (e.g., Holm and Hochberg tests) and fixed-sequence tests with applications to dose-ranging studies.
3. Resampling-based multiplicity adjustment method introduced by Westfall and Young and subtleties of its use in clinical trials with continuous and binary endpoints.
4. Statistical methods for the analysis of clinical trials multiple primary endpoints, including popular global tests and tests for identifying the drug effect with respect to individual endpoints.
5. Multiple testing procedures for clinical trials with hierarchically ordered objectives, for example, clinical trials with multiple primary and secondary objectives. Efficient solutions for multiplicity problems of this kind can be obtained using "gate keeping strategies" when the primary analyses are treated as gatekeepers and the secondary analyses are performed only if one or more gatekeeper analyses have yielded a significant outcome. Similar gate keeping strategies can be used in dose-ranging trials.

The introduced statistical methods will be illustrated using examples from clinical trials. The speaker will discuss regulatory considerations and cover software implementation of the described statistical approaches

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

**1:00 - 4:00 PM**

**Session C**

**Statistical Analysis and Data Display** 

**Speakers: Professors Richard M. Heiberger & Burt Holland**

**Temple University, Philadelphia, PA**

**Moderator: Walter R. Young**

A dataset is always more easily understood by looking at appropriately drawn graphs than by examining tabular summaries. Explaining statistical conclusions succinctly to non-statisticians is easier with well-constructed graphs than with tabular output. In the speakers' opinion, graphs are the heart of most statistical analyses; the corresponding tabular results are formal confirmations of our visual impressions. Many graphs useful in performing statistical analyses are shown, and how to construct and interpret these graphs and relate them to the tabular output that appears automatically when a statistical program "analyzes" a data set will be discussed. Many of these graphs are our own inventions stemming from the writing of our text, or developed following its publication. The graphs cannot be automatically produced by existing software and so must be requested using command language. Throughout the presentation, a number of fundamental principles used to construct graphs; including proper scaling and use of symmetry, Cartesian products, and the trellis paradigm will be discussed and emphasized. The website accompanying the text contains code for constructing all its graphs, and this code may be used as templates for constructing new graphs.

**Session D**

**Hierarchical Bayes Methods & Software for Data Analysis**

**Speaker: Professor Bradley P. Carlin**

**University of Minnesota, Minneapolis, MN**

**Moderator: Ivan Chan**

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 tutorial introduces hierarchical 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. The speaker will also provide an introduction to and live 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 spatio-temporal estimation and mapping), where the MCMC Bayesian approach often provides the only feasible alternative that incorporates all relevant model features. Attendees 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. However, any significant previous exposure to Bayesian methods or Bayesian computing will not be assumed. The tutorial 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.

Session Titles with  are based on a book, which is available from the conference.

7 PM Speaker's Dinner (Extra Fee Event)

**Session E**

**QTc Panel - Early Cardiac Safety Signals in Clinical Research:**

**Speakers: Marilyn Agin, Scott Patterson, Joanne Zhang**

**Moderator: Alfred H. Balch**

Update on Release of Revised Draft (Step 4) ICH<sup>1</sup> Guidance: *The clinical evaluation of QT/QTc interval prolongation and proarrhythmic potential for non-antiarrhythmic drugs.*

The newest version of the Draft ICH Guidance addresses issues for standardized trials that are designed to ensure safety with respect to cardiac repolarization.

This version covers many statistical issues: categorical/outlier analysis, analysis of central tendency, patient-population to be enrolled, baseline adjustment, adjustment for heart rate and other relevant patient covariates, use of noninferiority intervals, choice of relevant clinical tolerance limits and the decision whether to use a parallel or crossover trial design.

A new section addressing alternatives to a the defined “well-controlled” QTc study has been added In this session we will have a presentation on the E14 guidance, and changes followed by the PHARMA and FDA panelist review. Then each panelist will have an opportunity to present his or her perspective on QT safety studies. The panel will then have a general floor discussion on E14 and related safety issues.

**Marilyn Agin** is Associate Director, Pfizer Global R&D, Co-Chair PHARMA QT-SET, **Scott Patterson** is Director, Glaxo SmithKline Pharmaceuticals Co-chair of the PhRMA QT-SET and author of a book on Clinical Pharmacology., **Joanne Zhang**, is Mathematical Statistician, QMR/CDER/FDA, is has publications on Nonlinear-Mixed effects models in QTc-Prolongation models.

**Session F**

**Fundamentals of Longitudinal Data Analysis** 

**Speaker: Professor Gerald van Belle**

**University of Washington, Seattle, Washington**

**Moderator: Jackie Kennedy**

This tutorial deals with the fundamentals of longitudinal data analysis beginning with the fact that there are at least two sources of variability. The two sources are conveniently epitomized by *between* and *within* subject variation. One of the most challenging steps, often ignored, is to describe how the data are generated. Four situations are envisaged. First, longitudinal data arising from controlled laboratory experiments. Second, data coming from randomized clinical trials. Third, data associated with cohort studies and finally, data generated in a longitudinal registry. These four situations describe the data signature or pedigree; they indicate increasing loss of control of the design structure. The implications for analysis will be spelled out. Three kinds of endpoints are dealt with: categorical, ordinal, and measurement. The session begins by exploring the variability between and within subjects emphasizing a graphical approach. The next step is based on an analysis of derived variables such as the slope of the response, or more generally, orthogonal polynomials as a paradigm of a derived variable. Then the tutorial moves to a more detailed examination of within-subject variability and regression methods as a way of characterizing this variability. This leads naturally to a consideration of types of missing data and their effect on statistical inference. How to handle missing data is emphasized. Additional topics covered: testing assumptions of the longitudinal model and presentation of results. The following more advanced topics will be mentioned briefly: non-linear mixed models, models for survival and repeated measurements, and models for time-dependent covariates. Data sets personally dealt with by the speaker will motivate the issues and analytic techniques.

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

**1:00 - 4:00 PM**

**Session G**

**Pharmacoepidemiology, An Overview**

**Speaker: Yi Tsong, Ph. D.**

**Office of Biostatistics, CDER, FDA**

**Moderator: William Wubao Wang**

Because of the many limitations of clinical trials, management of drug safety relies heavily on the information collected after the drug is on the market. Post marketing safety management plays an important role in risk management of a drug product. Post marketing safety management often consists of the following elements, safety and usage projection, safety signaling with ADR reporting system, meta analysis of clinical safety information and epidemiologic observational study. Safety and usage projection may be carried out at all stages of the life cycle of a new drug. In the pre-marketing stage, the information may be used in pre-marketing assessment of benefit and risk of a new treatment. In the post marketing stage, it can be used in managing the safety of the drug in patients with usage different from that studied in the clinical trials. Signaling based on ADR reporting system is a tool often used to identify drugs that have been reported with outlying patterns among thousands of drugs in the market. It can be further used with usage data to signal potential drug safety problem. With multiple clinical trials available in the post marketing stage, a meta analysis is often used to assess and update the safety of the drug of interest and helps to assess safety difference among heterogeneous patient populations. With the understanding that the usage of the drug is often different from the clinical trials, epidemiological observational studies are extremely important to manage the safety in patients treated instead of patients to be treated. A few case studies will be used to illustrate the applications.

**Session H**

**Statistics for Experimenters** 

**Speaker: Professor J. Stuart Hunter**

**Princeton University**

**Moderator: Walter R. Young**

John Wiley published the first edition of “Statistics for Experimenters” by Box, Hunter and Hunter in 1978. After 27 years and over 30 reprints, a second edition has appeared of this popular textbook and reference. The new edition is dedicated to one of its authors, William G. Hunter (1937-1986), a wonderful teacher, the founder of the Statistics Division of the ASQ, a vigorous advocate of a team approach to problem solving and an early admirer of W. Edwards Deming. The book will be reviewed giving special emphasis to the insights into the scientific method contributed by its senior author George Box. Of course, much has happened in the practice of statistics in the time period between the two editions. New topics to be discussed are the graphical analysis of variance plots, design projectivity, the simplification of data transformation by lambda plots, the use of split plot arrangements for insuring product robustness, the proper analysis of Plackett and Burman designs, a Bayesian approach to the problem of discrimination between models and a Bayesian method for selecting experimental runs sequentially in the light (dark?) of data already in hand. Sequential experimentation and the importance of hands-on experience on the part of students first learning the art of experimental design will also be discussed.

**Session I**

**Linear, Logistic, Survival, and Repeated Measures** 

**Speakers:** Professors Stephen C. Shiboski & Charles E. McCulloch  
**Biostatistics Division, University of California, San Francisco**  
**Moderator:** Jackie Kennedy

Regression methods for continuous, binary, survival and repeated measures outcomes are among the most commonly applied analysis approaches for data arising in medical research. Although these are traditionally treated in distinct courses, researchers interested in practical applications benefit from learning them together, with an emphasis on common features in model construction, diagnostics and interpretation, and on the use of standard software packages for data analysis. The textbook covers each of these methods in detail, using research questions and data from actual clinical and epidemiological studies for motivation and illustration. The tutorial will follow the presentation in the book, with the goals of providing an overview and real examples of each technique, as well as discussing the common features that make their application clearer. We will also briefly cover links between these methods and the unifying concept of generalized linear models, model selection techniques, and the supplemental use of computationally intensive methods for diagnostics and inference, such as the bootstrap and nonparametric smoothing methods. Although the examples will largely be drawn from the medical sciences, applicability to a broader range of research questions will be emphasized.

**Session J**

**Nonparametric Methods For The Analysis Of Data From Cross-Over Trials With Two Or More Treatments** 

**Speaker:** Professor Byron Jones  
**Pfizer Global Research and Development, Sandwich, UK**  
**Moderator:** Alfred H. Balch

After first reviewing the methodology of the Wilcoxon rank-sum test and the construction of Hodges-Lehmann estimators and confidence intervals, the speaker will describe how these methods can be used to analyse data from a two-treatment, two-period cross-over trial. The extension of this methodology to the case of stratified data, leading to the well-known Van Elteren test and corresponding estimators and confidence intervals, will then be described. It will then be shown that for a certain subclass of cross-over designs this stratified analysis can be applied to cross-over trials with more than two treatments. Examples will be given for a design with three treatments in three periods and six sequences and a design with four treatments in four periods. Variations on the form of the stratified analysis will be illustrated using these examples. An approach that can be applied to a wider class of cross-over designs, based on permutation testing and bootstrap estimation, will then be described and illustrated. The methods described will be particularly appropriate for the analysis of  $T_{max}$ , the time to maximum concentration in a bioequivalence study as well as more general situations where nonparametric methods are appropriate. Examples of data from real trials will be used throughout the presentation.

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

**1:00 - 4:00 PM**

**Session K**

**Handling Drop-Out In Longitudinal Clinical Trials**

**Peter Lane**

**Research Statistics Unit, GlaxoSmithKline, Harlow UK**  
**Moderator:** Nandita Biswas

Missing data is a pervasive issue in clinical trials, as in many other applications of statistics. There are many approaches to dealing with it, ranging from putting your head in the sand, to computer- and time-intensive analysis of potential mechanisms for missingness. Longitudinal trials provide a particularly fertile area for making use of a range of statistical approaches and a comparative overview of many of these will be given. When it comes to a decision about how to handle drop-out in the primary analysis of a longitudinal trial, in which the main goal is to compare treatments at a single time-point, two particular methods are prominent. The LOCF or last-observation-carried-forward method, that has been used for many years; and the MMRM or Multivariate (or Mixed) Repeated Measurement method that is being proposed increasingly more often will be described in detail. The two will be compared in the context of a collection of recent trials in the Psychiatry therapeutic area, which have been reanalysed and used as a basis for an extensive simulation study. When drop-out is not ignorable, no single method can provide a satisfactory analysis on its own. A strategy for sensitivity analysis to accompany a primary analysis, using more complex methods that necessarily rely on untestable assumptions will be outlined.

**Session L**

**Latent Class Model And Its Clinical Application**

**Speaker:** Professor Charles E. McCulloch  
**University of California @ San Francisco, CA**  
**Moderator:** William Wubao Wang

The linear mixed model is a well-known method for incorporating heterogeneity (for example subject to-subject variation) into a statistical analysis for correlated continuous responses. However heterogeneity cannot always be fully captured by the usual assumptions of a normally distributed random effect. Latent class models have a long history and offer a way of incorporating additional heterogeneity in the form of distinct, latent subgroups. These latent subgroups are used to model mixture distributions, for example latent diseased and non-diseased subpopulations. They can be either exploratory in nature, when the focus is on the unobserved latent classes, or may support more formal statistical inference. Latent class models can be used in a variety of situations. They can be used to describe responders and non-responders to treatment, to describe distinct longitudinal growth trajectories, are a strategy for handling possibly informative missing data and are a way to test for adequacy of random effects distributional assumptions. Recent advances in software allow the use of this class of models with non-normally distributed outcomes and outcomes of mixed types.

This tutorial will describe the use of latent class and latent class mixed models and illustrate a variety of biomedical situations in which they can be applied. The focus will be on practical application of the techniques and interpretation of the results. Some of the software available for fitting these models will be discussed.

**TWO SIMULTANEOUS SHORT COURSES  
THURSDAY AND FRIDAY, DECEMBER 8-9, 2005**

**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

**An Introduction to Generalized Linear Mixed Models**

**Instructor: Charles E. McCulloch, Ph.D.**

**Biostatistics Division, University of California, San Francisco**

**Moderator: Dr. William Wubao Wang**

**Text: Generalized, Linear, and Mixed Models**

**Day 1 of the course will cover:**

- Introduction
- Review: Linear Mixed Models and Generalized Linear Models
- Introduction to Generalized Linear Mixed Models (GLMMs)
- Modeling in GLMMs

**Day 2 of the course will cover:**

- Features of GLMMs
- Inference for GLMMs
- Case Studies
- Summary/Discussion

The class of generalized linear mixed models (GLMMs) is a broad class of statistical models generalizing both linear mixed models (LMMs) and generalized linear models (GLMs). As such it is capable of accommodating nonlinear responses, correlated data and non-normal distributions. This makes it quite useful in practice. For example, GLMMs give a natural way to specify a correlated data model for binary data.

The course will briefly review the concepts of linear mixed models and the use of random effects as well as the modeling strategy behind generalized linear models. From these two classes of models will be developed generalized linear mixed models. A series of examples will be considered to develop intuition about how to specify these models in real situations. Next, features of generalized linear mixed models will be developed and strategies for fitting the models to data will be described and contrasted with approaches such as generalized estimating equations. A series of case studies will be used to illustrate the practical use of these models. The focus in the course will be on approaches to modeling, methods of estimation and inference, and available software.

**Charles McCulloch, Ph.D.** is a Professor and Head of the Division of Biostatistics at the University of California, San Francisco and was previously Professor and the founding Chair of the Department of Statistical Science at Cornell University. He is the co-author of the texts “Variance Components,” “Generalized, Linear, and Mixed Models” and “Regression Methods in Biostatistics: Linear, Logistic, Survival, and Repeated Measures Models” and the author of the statistics monograph “Generalized Linear Mixed Models”. He is a fellow of the American Statistical Association and an elected member of the International Statistical Institute.

**Bioequivalence & Statistics in Clinical Pharmacology**

**Instructors: Scott Patterson (GlaxoSmithKline)**

**Professor Byron Jones (Pfizer)**

**Moderator: Dr. Alfred H. Balch**

**Text: Bioequivalence and Statistics in Clinical Pharmacology**

**Day 1 of the course will cover:**

- Drug Development and Clinical Pharmacology
- History and Regulation of Bioequivalence
- Testing for Average Bioequivalence
- Non-Standard Designs for Demonstrating Bioequivalence
- The Future and Recent Past of Bioequivalence Testing

**Day 2 of the course will cover:**

- Clinical Pharmacology Safety Studies
- ECG Monitoring and Studying QTc Prolongation
- Population Pharmacokinetics
- Clinical Pharmacology Efficacy Studies

This course will cover the application and basic elements of the theory of statistical methods in clinical pharmacology. The first day will cover the techniques used in the assessment of bioequivalence - the study of a drug formulation to confirm its equivalence to another. The second day will cover the use of statistics in clinical pharmacology studies of safety, ECG monitoring, efficacy, and population pharmacokinetics. The emphasis will be on study design, analysis, and interpretation of data using real-data examples from the authors' experiences. The course will provide: (1) a wide range of real examples with datasets, SAS and SPLUS code, which will be available from the web, (2) applications of statistics in clinical pharmacology drug development with an emphasis upon regulatory applications and (3) a detailed consideration of the statistical analysis and design of bioequivalence and clinical pharmacology studies.

**Scott Patterson, Ph.D.** is the Director of Biomedical Data and Statistical Sciences for Cardiovascular and Urology Drug Development at GlaxoSmithKline Pharmaceuticals and previously directed the department of Clinical Pharmacology Statistics in Philadelphia at SmithKline Beecham. He is an expert on the design and statistical analysis of Clinical Pharmacology trials. He is a co-founder and past chair of the Pharmacometrics and Biostatistics Section of the American Society of Clinical Pharmacology and Therapeutics and has over 10 years of statistical consulting and collaborative experience in pharmaceutical research and development.

**Byron Jones, Ph.D.** is a Senior Director in the Statistical Research and Consulting Centre at Pfizer Global Research and Development. He is an expert in the design and statistical analysis of cross-over trials and co-authored the classic text on this topic, in addition to his book on Statistical Inference. He has over 20 years of statistical consulting and collaborative experience.

## Committee

<b>Chairman &amp; Program Registrar</b> Walter R. Young* 16 Harrow Circle Wayne, PA 19087 (610) 989-1622 walter.young10@verizon.net	<b>Registrar</b> William I. Martin Customized Management Systems, Ltd. 18-65 211 St., Suite 2F Bayside, NY 11360-1814 (718) 631-2375 Fax # (718) 631-2375 dem-cms@att.net	<b>Publicity</b> Joseph G. Borden New York City Transit 50 Battery Place Apr 8J New York, NY 10280 (646) 252 3940 Fax # (646) 252-4911 joborden@nycct.com	<b>Arrangements</b> Satish Laroia Larson Associates 33 Aspen Circle Edison, NJ 08820 (973) 812-9033 Fax # (732) 549-7487 satish.laroia@amide.com	<b>Bibliolator</b> Wenjin Wang, Ph.D. Wyeth Research P.O. Box 42528 Philadelphia, PA 19101 (484) 865-2201 Fax # 484-865-0072 wangw@wyeth.com	<b>Web Master</b> Kalyan Ghosh, Ph.D. Merck Research Laboratories BL3-3 West Point, PA 19486 (484) 344-7635 Fax # (484) 344-2931 kalyan_ghosh@merck.com
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## Program Committee

Dr. Alfred H. Balch Novartis Pharmaceuticals 59 Route 10 E. Hanover, NJ 07936-1080 (862) 778-7639 Fax # (973) 781-6498 fred.balch@pharma.novartis.com	Dr. Nandita Biswas GlaxoSmithKline 2301 Renaissance Boulevard Building #510, RN 0420 King of Prussia, PA 19406 (610) 787-3838 Fax # (610) 787--7004 nandita.biswas-1@gsk.com	Dr. Ivan Siu Fung Chan Merck Research Laboratories P.O. Box 4 Mail Stop UNA-102 West Point PA 19486 (484) 344-3391 Fax # (484) 344-7105 ivan_chan@merck.com	Professor J. Stuart Hunter 17-3U Meadow Lakes Hightstown, NJ 08520 (609) 426-6082 Fax # (609) 443-1506 stuhunt@bellatlantic.net	Jacqueline Kennedy Wyeth Research P.O. Box 42528 Philadelphia, PA 19101 (484) 865-2083 Fax # (484) 865-0066 kennedj1@wyeth.com	Dr. William Wubao Wang Merck Research Laboratories P.O. Box 4 Mail Stop UNA-102 West Point PA 19486 (484) 344-3005 Fax # (484) 344-7105 william_wang@merck.com
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**\*Walter R. Young has chaired the conference for thirty-six consecutive years.**

## REGISTRATION

**Mail or FAX the Below Form or Register Online at [www.demingconference.com](http://www.demingconference.com)**

Please register as early as possible. Payment must accompany the form either by check, which must be included, or by credit card number. Registration confirmation will be given by phone or FAX. 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 receipts will be sent upon request.

On site conference registrations start at 7:30 AM December 5<sup>th</sup> through December 7<sup>th</sup> and at 8 AM on December 9<sup>th</sup>. Transmit registration to **Mr. William I. Martin, Customized Management Systems, Ltd., 18-65 211 St., Suite 2F, Bayside, NY 11360-1814**. You may FAX a **copy** of the registration form to: (718) 631-2375. **Do Not Attempt to FAX the Orange Form as this Does Not Work.**

Last Name: _____	First Name: _____	Mr. <input type="checkbox"/> Ms. <input type="checkbox"/> Mrs. <input type="checkbox"/> Dr. <input type="checkbox"/> Other <input type="checkbox"/>
Organization Name: _____		Mailing Address: _____
City: _____	State: _____	Zip: _____
Daytime Telephone: _____	Facsimile: _____	E-mail: _____

Please Indicate which Conference Tutorial Sections You Plan to Attend:

A <input type="checkbox"/>	C <input type="checkbox"/>	E <input type="checkbox"/>	G <input type="checkbox"/>	I <input type="checkbox"/>	K <input type="checkbox"/>
B <input type="checkbox"/>	D <input type="checkbox"/>	F <input type="checkbox"/>	H <input type="checkbox"/>	J <input type="checkbox"/>	L <input type="checkbox"/>

Registration for Conference Tutorial	On or Before <u>Oct. 1<sup>st</sup></u>	On or Before <u>Nov. 1<sup>st</sup></u>	After <u>Nov. 1<sup>st</sup></u>	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	_____
Speaker Dinner, Monday 7:00 PM	\$40	\$45	\$50	_____
<b>Short Courses:</b>				
An Introduction to Generalized Linear Mixed Models	\$675	\$740	\$805*	_____
Bioequivalence and Statistics in Clinical Pharmacology	\$675	\$740	\$805*	_____
<b>Book Order Total (see reverse page)</b>	_____			
<b>Total Registration and Book Order</b>	_____			

**Cancellations will be accepted until November 18<sup>th</sup> for a \$50 fee.**

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

**TRAVEL TO THE CONFERENCE**

**AIR:** Non-discount fares are usually much lower to Atlantic City (ACY) than to Philadelphia (PHL) but you should check both airports to search for the best fare and connections. Advance reservations with Royal Airport Service, (888) 824-7767, are cheaper than a cab to and from ACY. The cheapest connection from PHL is the below referenced SEPTA, but this will take about two hours. Royal Airport Service, while appreciably more expensive, takes about an hour and is probably cheaper than renting a car ([www.bnm.com](http://www.bnm.com)) that is unnecessary in Atlantic City. Discount airlines not on the major search engines such as Spirit, [www.spiritair.com](http://www.spiritair.com), to ACY; and AIRTRAN, [www.airtran.com](http://www.airtran.com); America West, [www.americawest.com](http://www.americawest.com); ATA, [www.ata.com](http://www.ata.com); Frontier, [www.frontierairlines.com](http://www.frontierairlines.com); Southwest, [www.southwest.com](http://www.southwest.com); and USA 3000, [www.usa3000airlines.com](http://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.

**RAIL:** NJ Transit has relatively frequent local (14 daily trips with 6 stops) service to Philadelphia connecting with Amtrak and SEPTA at 30<sup>th</sup> Street and PATCO at Lindenwald, NJ. Free shuttle busses meet all trains and provide direct service to all casinos. For a schedule, see [www.nj.com/njtransit/acl.htm](http://www.nj.com/njtransit/acl.htm). This schedule also shows the R1 SEPTA connections to PHL at 30<sup>th</sup> Street.

**BUS:** Check your local paper or call the casino bus transportation departments for Atlantic City transportation information. 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 jitney on Pacific Avenue to quickly and cheaply get to the Tropicana. [www.greyhound.com/products\\_services/casino\\_nj.shtml](http://www.greyhound.com/products_services/casino_nj.shtml) will give you information on Greyhound's service directly to the Tropicana with a 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 Atlantic Avenue. Make a right onto Atlantic Avenue. Travel South on Atlantic Avenue to Brighton Avenue and enter the Transportation Center on the right. There is a \$4 per day fee charged by Atlantic City that will allow you to casino hop until 6:00 AM the following morning. However, if you leave your car in the garage for the duration of the conference, there is only a one time \$4 fee.

**PROMOTIONS:** Check your local Sunday paper for coupons. The Philadelphia Inquirer prints show and meal discount coupons both Friday and Sunday. Check [www.tropicana.net](http://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](http://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. 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](http://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 during our morning break at 10 AM as well as an afternoon refreshment break at 2:30 PM. Also, there will be an optional subsidized Speaker Dinner on Monday.