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

Sponsored by
AMERICAN SOCIETY FOR QUALITY
NY/NJ Metropolitan Section ~ ~ Statistics Division
AMERICAN STATISTICAL ASSOCIATION: Biopharmaceutical Section
December 04 – December 06, 2017: Three-Day Conference
Tropicana Casino and Resort, Havana Tower, Atlantic City, NJ

Short Courses: – December 07-08, 2017

1. GUIDE Approach to Subgroup Identification and Analysis for Precision Medicine (Professor Wei-Yin Loh, University of Wisconsin)

2. Multiplicity Issues in Clinical Trials (with book, Dr. Alex Dmitrienko, Mediana, Inc.)

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

ONSITE REGISTRATION WILL BE ON THE FOURTH FLOOR OF THE HAVANA TOWER.
It will start at 6:00 pm on Sunday December 6th and will be followed by a one-hour reception with cold drinks and snacks.
It will continue at 7:30 AM Monday December 7th through Thursday December 10th.
THREE-DAY REGISTRANTS WILL RECEIVE A BOUND COPY OF THE HANDOUTS FOR ALL SESSIONS.
RECEIPTS and a CERTIFICATE OF ATTENDANCE will be distributed at the conference. Register and pay for both the conference and the hotel online as early as possible at www.demingconference.com. This gives you an instant email acknowledgement. Only if absolutely necessary, mail a check with your completed registration form on page 7 in this program. If checks aren't postmarked on or before the early discounted registration date, you will be charged the next higher amount. E-Mail Cancellations sent to registration@demingconference.com will be accepted until November 16th for a separate $100 fee each for the conference and courses registered. Afterwards, there will be no refunds but substitution of another registrant is permissible. Book orders can't be cancelled. If a registrant cancels, his or her ordered books would be mailed.

We are soliciting abstract proposals for posters via email to the registrar. The Poster Presentation forum, allows participants to submit their research concepts and issues of relevance for peer review in the area of biostatistics. Poster sessions, which will be held on all 3 days of the conference, allow attendees to discuss the specifics of an abstract with the author in a small group setting. Accepted poster abstracts will be published on both the website and in the transactions. Submissions will be accepted through Saturday, October 31, 2017. Full details and tips for presentation, are on our website. We will hold poster sessions, providing a forum to attendees to present concepts and issues of relevance to their peers. Abstracts can be submitted online or emailed to registration@demingconference.com for consideration.

Walter R. Young
Chairman
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Monday, December 04, 2017; 8:00 am – 9:00 am

Key Note: Roles of Biostatisticians In New Drug Development and Regulatory Review

Dr. Yuki Ando; Senior Scientist for Biostatistics; Pharmaceuticals and Medical Devices Agency; Japan
Moderator: **Dr. Naitee Ting**

Morning Session 9:30 – 12:15 AM

Session A
Hot Topics in Clinical Trials: Multiple Outcomes and Benefit: Risk

Dr. Toshimitsu Hamasaki, Osaka University and National Cerebral and Cardiovascular Center, Japan; **Dr. Scott R. Evans**; Harvard School of Public Health
Moderator**: Dr. Ivan S. F. Chan**

We discuss two hot topics in clinical trials. In Part I we discuss the design and analysis of clinical trials with multiple outcomes. In Part II, we discuss benefit to risk evaluation in clinical trials by using outcomes to analyze patient rather than patients to analyze outcomes. PART I: The effects of interventions are multidimensional. Use of more than one outcome offers an attractive design feature in clinical trials as they capture more complete characterization of the benefit and risk of an intervention and provide more informative intervention comparisons. The tutorial will focus on design and analysis of clinical trials with such multiple outcomes. The first part of the tutorial will focus on methods for clinical trial designs evaluating efficacy of two interventions with multiple primary endpoints, especially multiple co-primary endpoints. PART 2: In part II of the tutorial, we will describe a broad vision for the future of clinical trials consistent with increased pragmatism. Greater focus on using outcomes to analyze patients rather than patients to analyze outcomes particularly in late-phase/stage clinical trials is an important part of this vision.

Session B
Missing Data Analysis Using SAS®

Dr. Frank Liu, Merck**; Dr. Fang Chen,** SAS® Institute
Moderator**: Dr. Xiaoming Li**

Proper addressing missing data in clinical trial analysis remains complex and challenging, despite a great amount of research that has been devoted to this topic. Conventionally, under the missing at random (MAR) assumption, we often use maximum likelihood or multiple imputation based methods for inferences. However, the MAR assumption is unverifiable from data and has been deemed by regulatory agencies to be overly-simplistic and unrealistic. On the other hand, missing not at random (MNAR) demands more sophisticated modeling treatments and estimation techniques. This tutorial covers various methods that have been advocated in dealing with missing data and illustrates how to carry out the analyses using SAS software. Examples will be presented using SAS/STAT software, including PROC MIXED, PROC MI, PROC GEE, and PROC MCMC. Outlines: 1. Review missing data analysis 2. Common analysis methods with example: * Restricted maximum likelihood (REML) * Mixed-effects Model Repeated Measure (MMRM), * constrained Longitudinal Data Analysis (cLDA) * GEE and wGEE * Multiple imputation (MI) * Bayesian approach 3. Recently-developed methods * Alternative and sensitivity analysis models * Control-based imputation * Tipping point analysis

Afternoon Sessions 1:15 - 4:15 PM

Session C
Regulatory Science and Drug Development in China

Professor **Naiqing Zhao,** Fudan Univ.; Dr. **Jie Chen,** Merck
Moderator**:** Dr. **Xiaoming Li**

There have recently been dramatic changes on government regulations in drug development in China. For instance, China Food and Drug Administration (CFDA) recently revised its Provisions for Drug Registration (PDR) requiring no prior overseas approval for new drug application in China. Under the new version of PDR, many technical guidelines governing drug development processes are being revised. In addition, the regulatory agency starts accepting data from multi-regional clinical trials with reasonable number of Chinese patients for new drug approval. China has submitted an application for an official seat in the International Conference on harmonization (ICH) community.

This tutorial will cover the following aspects:

(1) An overview of biopharmaceutical research, development and regulation in China
(2) An overview of drug approval process
(3) Introduction to the new PDR
(4) Statistical guidance for clinical trials
(5) Guideline for multi-regional clinical trials;
(6) General considerations for clinical trial applications (IND)
(7) General considerations for new drug applications (NDA)

During the discussion, numerous examples will be given for different circumstances in both IND and NDA.

Session D 🕮
Phase II Clinical Development of Drugs

Dr. **Naitee Ting** Boehringer Ingelheim; Dr. **Shuyen Ho,** UCB
Moderator: Dr. **Ivan S. F. Chan**

In the process of medicine discovery and development, understanding the dose-response relationship is one of the most important and challenging tasks. It is critical to identify the right range of doses in early stages of medicine development so that Phase III trials can be properly designed to confirm appropriate dose(s) for the patient. Usually in the beginning of Phase II development, there is limited information to help guide trial designs, therefore Phase II clinical trials often consists of objectives for establishing proof of concept (PoC), identifying a set of potentially safe and efficacious doses, and characterizing the dose-response relationship.

Some of the major challenges in designing these Phase II trials include the selection of dose range and frequency, clinical endpoints and/or biomarkers, and the use of control(s). Inappropriate Phase II trial designs may lead to delay of the medicine development program or waste of investment. Specifically, misleading results from poorly designed Phase II trials could force a Phase III program to confirm sub-optimal dose(s), or even stop developing a potentially useful medicine. Therefore, it is critical to consider Phase II trial designs, in the broader context of the entire medicine development plan, to make the best use of all available information, and to engage relevant experts. This presentation will focus on these perspectives.

7 PM Speaker's Dinner (Optional Added Fee Event)

Tuesday, December 05, 2017; 8:00 am – 9:00 am

Key Note: Bridging Study Evaluation and MRCTs in Taiwan: Regulatory Perspectives and Experiences

Dr. Guei-Feng Tsai; Statistical Team Leader; Division of New Drugs; Center for Drug Evaluation; Taiwan
Moderator: **Dr. Naitee Ting**

Morning Session 9:30 – 12:15 AM

Session E 🕮
Generalized Linear Models

Professor **Alan Agresti,** University of Florida
Moderator: Dr. **Wenjin Wang**

This short course presents an overview of generalized linear modeling (GLM). After introducing basic results for GLMs, we present GLMs for four types of response variables: continuous responses, binary responses, multi-category responses, and count responses. Primary emphasis is on gamma regression for positive, skewed responses, logistic regression for binary response data, cumulative logit models for ordinal responses, and negative binomial regression for count responses. The presentation emphasizes interpretation rather than technical details. Examples primarily use R, with some examples also using SAS. The material covered is in Chapters 4-7 of the book "Foundations of Linear and Generalized Linear Models" (Wiley, 2015) by Alan Agresti

Session F
Likelihood-Based Methods for Continuous Safety Monitoring of Pharmaceutical Products

Dr. **William Wang,** Merck; Dr. **Krishan P. Singh**, GSK; **Dr. Ram Tiwari,** FDA, On Behalf of the ASA Safety Monitoring Working Group
Moderator: Dr. **Kalyan Ghosh**

Continuous safety monitoring is a fundamental part of the drug development and life cycle management. Regulatory guidance, such as ICH E2C, ICH M4E(R2), FDA IND safety reporting guidance (2012, 2015) and the upcoming ICH E19 (under development) highlight the importance of valid statistical methodology for signal detection, analysis and reporting. In particular, safety monitoring requires a holistic, accumulative and dynamic approach of integrating medical judgment with quantitative evidence. From statistical perspectives, the likelihood approach provides a robust way to integrate the quantitative evidence, either in the Frequentist framework or in the Bayesian framework of incorporating data-driven objectivity and experience-driven subjectivity.

This tutorial session will examine the application of likelihood principles in safety monitoring. This includes (1) A primer on the likelihood principles under Frequentist/Bayesian frameworks; (2) Likelihood approach for blinded safety monitoring; and (3) Likelihood Ratio based methods for safety monitoring; We will also discuss and demonstrate the dynamic visual analytical implementation of these safety monitoring approaches using R*Shinny.

Afternoon Sessions 1:15 - 4:15 PM

Session G
ICH E17 and Multi-Regional Clinical Trials (MRCTs)

Dr. **William Wang**, Merck, Dr. **Yuki Ando**, PMDA , Japan
Moderator: Dr. **Kalyan Ghosh**

Drug development has rapidly been globalized. Multi-regional clinical trial (MRCT) for regulatory submission has widely been conducted in the ICH and non-ICH regions. Regulatory agencies currently face challenges in evaluating data from MRCTs for drug approval. In order to harmonize points to consider in planning/designing MRCTs and minimize conflicting opinions, an ICH working group was established in late 2014 to create an international guideline for MRCT (ICH E17). In June 2016, a draft guidance entitled "E17 General Principles for Planning and Design of Multi-Regional Clinical Trials" was issued by the ICH for public comment. This tutorial session contains 3 parts: (1) review evolving regulatory landscape and background about the ICH E17; (2) discuss key principles and statistical considerations outlined in the draft ICH E17 (Step 2b); (3) learn the relevant concepts using case studies of multi-regional clinical trials. We welcome interactive questions and discussions.

Session H
Causal Inference in a Big Data World: Introduction to Parametric and Semi-Parametric Estimators for Causal Inference

Professor **Laura Balzer,** UMass Amherst
Moderator: Dr. **Alfred H. Balch**

At increasing velocity, volume and variety, we are generating, recording and storing unprecedented amounts of data. Along with its many challenges, Big Data present exciting opportunities to better understand risk factors, to build improved predictors, and to examine the causal relationships between variables. Still, there are many sources of association between two variables, including direct effects, indirect effects, measured confounding, unmeasured confounding, and selection bias. Methods to delineate causation from correlation are perhaps more pressing now than ever. This short course will introduce a "causal roadmap" to approach research questions: 1) clear statement of the scientific question, 2) definition of the causal model and parameter of interest, 3) assessment of identifiability – that is, linking the causal effect to a parameter estimable from the observed data distribution, 4) choice and implementation of estimators including parametric and semi-parametric, and 5) interpretation of findings. The focus will be on estimation with parametric G-computation, inverse probability of treatment weighting (IPTW), and targeted maximum likelihood estimation (TMLE) with SuperLearner. Participants will work through the roadmap using an applied example and implement these estimators in R during the workshop session.

Wednesday, December 06, 2017 – 8:00 am – 9:00 am

Key Note: Regulatory Hot Topics in Europe

Dr**. Frank Pétavy & Dr. Andrew Thomson;** Biostatistics and Methodology Support Specialized Scientific Disciplines Dept.; European Medicines Agency; London, UK

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

Morning Session 9:30 – 12:15 AM

Session I

Benefit–Risk Assessment and Utility of Real World Evidence in Medical Product Development and Life Cycle Management

Drs. **Weili He,** Abbvie; Dr. **Qi Jiang,** Amgen

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

Evaluation of a new treatment has always required a benefit-risk (B-R) assessment. Guidance on how to select specific B-R frameworks and quantitative methods, along with case studies and best practice sharing, is mostly focused on pre-marketing applications. This tutorial contains two parts. Part I covers the role of BR assessments in medicine development and regulation, key elements of BR evaluations in a product's life cycle, and general guidance. In addition, we will present practical examples, lessons learned, and best practices that illustrate how to conduct structured B–R assessment in clinical development and regulatory submission. With a goal of potentially expanding BR assessment to utilizing real world evidence (RWE), Part II presents the utility of RWE that could 1) help expedite generation of research hypotheses that sharpen the focus of clinical research, including the designs of randomized controlled trials (RCTs), 2) in pre-approval setting, augment conventional RCT data with data from patients whose diversity reflects real word practice, resulting in better insight on safe and effective use of innovation; and 3) in post-approval arena, RWE generated from long-term observation of patient outcomes will identify factors in safety, clinical effectiveness and personalization of care that are difficult to identify among short-term RCTs conducted among highly homogenous groups of patients.

Session J

Dose-Finding in Clinical Development

Dr. **Qiqi Deng,** Boehringer Ingelheim

Moderator: Dr. **Naitee Ting**

Dose Finding is a critical part in drug development. Traditionally, chronic disease and oncology development has distinct approach for dose finding. This tutorial will give an overview of the overall dose-finding process in both areas, and discuss the emerging trends. Different approaches for hypothesis testing of proof of concept and modeling in dose finding studies will be introduced at a high level, and demonstrated by examples. Pragmatic recommendations on dose range, number of doses, dose spacing and formulation will be given with supportive data and evidence. The instructor will also give her opinion and recommendations on the way to apply adaptive design elements within dose finding studies.

Afternoon Sessions 1:15 - 4:15 PM

Session K

Statistical & Strategic Considerations in Development of Oncology Immunotherapies

Dr. **Cong Chen**, Merck

Moderator: Dr. **Naitee Ting**

Oncology immunotherapies have the potential to be effective in more tumor indications than a non-immunotherapy, as demonstrated by PD-1 (or PD-L1) immune checkpoint inhibitors such as pembrolizumab and nivolumab in recent years. Following the success of PD-1 (or PD-L1) inhibitors, a flood of next generation immunotherapies with different mechanisms of action (e.g., LAG3, CD40, ICOS, TIM-3, IDO1, GITR, STING, OX40, TIGIT) are being developed. While the expectation is high for these new immunotherapies, it is unrealistic to expect all of them to have the same success as the immune checkpoint inhibitors. Even if they are indeed as effective as the immune checkpoint inhibitors, it will be challenging to demonstrate their clinical benefit given the improved standard-of-care. It is imperative to apply innovative and cost-effective statistical strategies to the development of these new immunotherapies. This tutorial will present the lessons and experiences learned from the development of the checkpoint inhibitors. It will also present statistical strategies on efficacy screening, design adaptation between Phase 2 and Phase 3, and adaptive biomarker enrichment design and platform/ basket design for Phase 3 trials.

Session L 🕮

Meta-Analysis and Network Meta-Analysis in Clinical Trials

Dr. **Joseph C. Cappelleri** (Pfizer) and Prof. **Din Chen** (UNC Chapel Hill)

Moderator: **Walter R. Young**

Results of several similar studies identified with a systematic literature review can be quantitatively synthesized via meta-analysis to obtain a pooled estimate on the outcome of interest and to evaluate its heterogeneity. In its basic form, a meta-analysis typically involves comparisons of two interventions for one particular endpoint, but can be expanded with multiple treatment comparisons or outcomes. This tutorial highlights and expounds upon five key and interrelated areas on meta-analysis: 1) impetus for systematic reviews and meta-analysis, 2) basic steps to perform a systematic literature review, 3) statistical methods of combining data, 4) reporting of results, and 5) appraisal and use of meta-analytic reports. In addition, network meta-analysis (indirect and mixed treatment comparisons) – and expansion of traditional meta-analysis for the same pairwise comparison – will be presented where a) its value will be discussed for coherent decision making; b) its concepts and assumptions, such as similarity and consistency, will be identified; and c) its statistical models will be described. The material throughout the tutorial is motivated and illustrated by instructive and real examples.

TWO SIMULTANEOUS SHORT COURSES THURSDAY AND FRIDAY, DECEMBER 07-08, 2017

Registration includes (1) a hot breakfast and two refreshment breaks each day; (2) handouts and (3) the text. No registrations will be accepted without payment in full. We will refund full tuition if courses are canceled due to insufficient registration.
8:00–9:30 Lecture 9:30–9:50 Break 9:50–11:20 Lecture 11:20–12:40 Lunch 12:40–2:10 Lecture 2:10–2:30 Break 2:30–4:00 Lecture
With the consent of the registrants, the first Friday session might be moved to Thursday afternoon to allow attendees time to catch their flights.

COURSE 1
GUIDE Approach to Subgroup Identification and Analysis for Precision Medicine

Presenter: Professor **Wei-Yin Loh**, University of Wisconsin
Moderator: Dr. **Ivan S. F. Chan**

Texts: Statistical Methods for Evaluating Safety in Medical Product Development Quantitative Evaluation of Safety in Drug Development – Design, Analysis & Reporting

A challenging statistical problem in drug discovery and development is identification of patient subgroups that exhibit differential treatment effects. To further our understanding of how a treatment works on a disease, it is helpful that the subgroups are interpretable, such as being defined by a small set of biomarkers and their associated threshold values. This can be a formidable task even if the objective is only to identify the biomarker subset (let alone finding the threshold values), when the set of potential biomarkers is large. Regression tree methods are natural solutions because the subgroups are defined by the terminal nodes of a decision tree.

Several regression tree algorithms exist for subgroup identification, but many have significant deficiencies. Algorithms based entirely on greedy search tend to increase the probability of identifying the wrong biomarkers, due to the latter being measured at higher levels of granularity. Further, algorithms that search for biomarker thresholds by maximizing a measure of the between-subgroup difference in treatment effects inevitably yield overly optimistic estimates that cannot be replicated. Finally, the vast majority of algorithms are inapplicable to data with missing values, to multivariate response variables, and to treatment variables with more than two levels.

GUIDE is an algorithm that is unique in these respects: (1) it has negligible bias in variable selection, (2) it has negligible bias in treatment effect estimation, (3) it is applicable to treatment variables with more than two levels, (4) it can control for effects of prognostic variables within subgroups, (5) it does not require imputation of missing values, and (6) it is applicable to multiple, longitudinal, and censored response variables.

Using a series of real examples, the course will discuss (i) why many algorithms have the abovementioned difficulties and how GUIDE overcomes them, (ii) the effect of multicollinearity and masking on subgroup identification, (iii) the meaning of a "subgroup" when there is no true subgroup, and (iv) the conceptual and statistical difficulties of post-selection inference, particularly for subgroup identification, and (v) a solution by means of bootstrap calibration. The last part of the course is a hands-on demonstration of the free GUIDE software, which can be obtained from http://www.stat.wisc.edu/~loh/guide.html. Attendees are encouraged to install the software and data sets on their computers beforehand.

COURSE 2
Multiplicity Issues in Clinical Trials

Presenter: Dr. **Alex Dmitrienko**, Mediana, Inc.
Moderator: Dr. **Alfred H. Balch**

Text: Multiple Testing Problems in Pharmaceutical Statistics

This two-day course focuses on a broad class of multiplicity problems arising in clinical trials and provides a comprehensive review of traditional and advanced methods for addressing multiplicity. The course begins a review of key concepts in multiple hypothesis testing, e.g., inferential goals in multiplicity problems, error rate definitions, closure principle and other principles for constructing MTPs (multiple testing procedures). A detailed summary of commonly used MTPs is provided, including nonparametric procedures with a data-driven or fixed testing sequence, semiparametric and parametric procedures. Additional topics of particular interest include simultaneous confidence intervals in multiplicity problems and sample size calculations in clinical trials with multiple objectives.

The second part of the course deals with more advanced multiplicity problems with several sources of multiplicity, e.g., problems arising in trials with multiple endpoints (first source of multiplicity) and multiple dose-control comparisons (second source of multiplicity). Gatekeeping procedures are commonly used in complex multiplicity problems. These procedures protect the overall Type I error rate and efficiently account for the hierarchical structure of individual tests. The following types of gatekeeping procedures will be discussed:

• Gatekeeping procedures with simple logical relationships (serial and parallel gatekeeping procedures), including general multistage parallel gatekeeping procedures.

• Gatekeeping procedures with general logical relationships among families of hypotheses, including chain procedures (graphical methods) and powerful mixture-based procedures.

The short course offers a well-balanced mix of theory and applications with case studies based on real clinical trials and discusses relevant regulatory considerations. Software tools for implementing popular multiple testing procedures will be presented, including custom SAS macros and R functions.

Selected references:

Dmitrienko, A., Tamhane, A.C. (2007). Gatekeeping procedures with clinical trial applications. Pharmaceutical Statistics. 6, 171-180.

Dmitrienko, A., Bretz, F., Westfall, P.H., Troendle, J., Wiens, B.L., Tamhane, A.C., Hsu, J.C. (2009). Multiple testing methodology. Multiple

Day 1 Morning session: Basic ideas of classification and regression trees
1. Classification with continuous predictors: glaucoma prediction
2. Classification with categorical predictors: peptide binding
3. Key differences between GUIDE and CART: heart disease
4. Longitudinal response variables: Alzheimer's disease
5. Importance scoring of predictor variables

Day 1 Afternoon session: Subgroup identification in randomized trials
1. No missing values: breast cancer
2. Large numbers of missing values: retrospective gene study
3. Longitudinal response: Type II diabetes
4. Importance scoring when treatment variable is present
5. Comparison of GUIDE with other tree and forest methods

Day 2 Morning session: Post-selection inference and local prognostic control
1. Conceptual difficulties of post-selection inference
2. Bootstrap calibrated confidence intervals
3. Bootstrap intervals for treatment effects
4. Local linear control of prognostic variables

Day 2 Afternoon session: Demonstration of GUIDE software
Free software, manual and sample data sets from
http://www.stat.wisc.edu/~loh/guide.html

References:
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Dmitrienko, A., Tamhane, A.C. (2009). Gatekeeping procedures in clinical trials. Multiple Testing Problems in Pharmaceutical Statistics. Dmitrienko, A., Tamhane, A.C., Bretz, F. (editors). Chapman and Hall/CRC Press, New York.

Dmitrienko, A., Tamhane, A.C. (2011). Mixtures of multiple testing procedures for gatekeeping applications in clinical trials. Statistics in Medicine. 30, 1473-1488.

Dmitrienko, A., D'Agostino, R.B., Huque, M.F. (2013). Key multiplicity issues in clinical drug development. Statistics in Medicine. 32, 1079–1111.

SPEAKER'S BIO

Alan Agresti (Honorary Doctorate from De Montfort University) is Distinguished Professor Emeritus of Statistics at the University of Florida. He is author or co-author of more than 100 articles and seven books, including "Categorical Data Analysis" (3rd ed. 2013), "Statistics: The Art and Science of Learning from Data"(4th ed. 2016), and "Foundations of Linear and Generalized Linear Models" (2015). He is a fellow of the American Statistical Association and of the Institute of Mathematical Statistics, Agresti has received the Statistician of the Year award from the Chicago chapter of the American Statistical Association.

Yuki Ando (Ph.D. in Health Science from Osaka University) is a Senior Scientist for Biostatistics of the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. In 1997, she joined the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC), which was established that year and subsequently transformed into the current PMDA. Currently she is responsible for the biostatistics review and consultation in the new drug and device review offices in PMDA. Additionally, she works as a leader of business part of Advanced Review with Electronic Data Promotion Group, the group which is responsible for the use of patient level electronic study data that are submitted with new drug applications in Japan. She is responsible for promoting CDISC implementation and the use of submitted electronic data in new drug review in PMDA.

Laura Balzer (PhD in Biostatistics from UC Berkeley) is an Assistant Professor of Biostatistics at the University of Massachusetts, Amherst. She completed her post-doctoral studies at the Harvard T.H. Chan School of Public Health. Her areas of expertise are Causal Inference and Machine Learning. She is the Principal Statistician for the SEARCH trial, a 320,000-person community randomized trial to evaluate a bold strategy for HIV testing and treatment in rural Uganda and Kenya (NCT01864603). Laura is also passionate about teaching introductory and advanced causal and statistical methods.

Joseph C. Cappelleri (Ph.D. in Psychometrics from Cornell University) is a senior director of biostatistics at Pfizer. He has also served on the adjunct faculties of Brown University, Tufts Medical Center, and the University of Connecticut. Dr. Cappelleri has delivered numerous conference presentations and has published extensively (approximately 400 publications) on clinical and methodological topics, including regression-discontinuity designs, health measurement scales, and meta-analysis. He was a member of the International Society for Pharmaco-economics and Outcomes Research (ISPOR) Task Force on Indirect Treatment Comparisons Good Research Practices. Dr. Cappelleri is an associate editor for the journal *Research Synthesis Methods*.

Cong Chen (Ph.D. in Statistics from Iowa State University) is Director of Early Oncology Biostatistics at Merck & Co., Inc. He joined Merck in 1999. He has published over 60 papers and 6 book chapters on statistical methodologies for design and analysis of clinical trials, including new paradigms for biomarker directed clinical development and Phase II proof-of-concept studies. His most recent accomplishment includes playing a pivotal role in regulatory approval of KEYTRUDA, a paradigm changing anti-PD-1 immunotherapy, for multiple indications. He is a Fellow of American Statistical Association, an Associate Editor of Statistics in Biopharmaceutical Research, a member of Cancer Clinical Research Editorial Board and a co-leader of the DIA Small Population Work Stream.

Din Chen (Ph.D. in Statistics from University of Guelph) is the Wallace Kuralt Distinguished Professor at the University of North Carolina-Chapel Hill. Dr. Chen is a fellow of American Statistical Association and a senior expert consultant for biopharmaceuticals and government agencies with extensive expertise in clinical trial biostatistics. Dr. Chen has more than 160 referred professional publications and co-authored/co-edited twelve books on clinical trials, interval-censored survival data analysis, meta-analysis, public health statistics, statistical causal inferences, statistical methods in big-data sciences and Monte-Carlo simulation-based statistical modeling.

Fang Chen (PhD in Statistics from Carnegie Mellon University) is a senior manager of Bayesian statistical modeling in the Advanced Analytics Division at SAS Institute Inc. Among his responsibilities are development of Bayesian analysis software and the MCMC procedure. He has taught many short courses previously at statistical meetings including JSM, ENAR, ICSA Applied Statistics Symposium, and Regulatory-Industry workshop.

Jie Chen, (PhD in Statistics from Temple University) Distinguished Scientist, Merck Research Laboratories, North Wales, Pennsylvania. Before rejoining Merck, Jie held various positions in biopharmaceutical companies including six-and-a-half-year experience in China and prior 14 years at Merck Research Laboratories in the US. Jie's experience includes clinical trial design and data analysis, statistical methodology research and applications in non-clinical, pre-clinical and clinical development, as well as safety evaluation in both clinical and post-approval settings. Jie received an MD from Shanghai First College of Medicine (now Fudan University College of Public Health), Shanghai, China.

Qiqi Deng (Ph. D. in Statistics from University of Minnesota.) is a Senior Principle Biostatistician at Boehringer Ingelheim Pharmaceutical. She is currently a member of the Methodology Expert team within global statistics, which focuses on statistical methodology innovation. Her research area includes hypothesis and modeling in dose finding, pragmatic considerations in designing dose finding trials, including adaptive design aspects. Before she joined the methodology group, she has served as leading statistician for multiple projects, across different clinical development phases and therapeutic areas.

Alex Dmitrienko, (Ph.D. in Statistics from University of Kentucky) is the President and Founder of Mediana Inc. Alex Dmitrienko has over 20 years of clinical trial experience and has been actively involved in biostatistical research with emphasis on multiple testing procedures, subgroup analysis and adaptive designs in clinical trials. He has published over 80 papers and authored/edited two SAS Press books (Analysis of Clinical Trials Using SAS and Pharmaceutical Statistics Using SAS) and a Chapman and Hall/CRC Press book (Multiple Testing Problems in Pharmaceutical Statistics). Dr. Dmitrienko is a Fellow of the American Statistical Association (2009). Dr. Dmitrienko has taught over 30 short courses on key topics in clinical trial statistics, including multiple comparisons, subgroup analysis and clinical trial optimization.

Scott R Evans (Ph.D. in Biostatistics from University of Massachusetts) is the Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG). His interests include the design, monitoring, analyses, and reporting of and education in clinical trials. He is the author of more than 100 peer-reviewed publications and three textbooks on clinical trials including Fundamentals for New Clinical Trialists. Dr. Evans is a member of an FDA Advisory Committee, the Board of Directors for the American Statistical Association, the Society for Clinical Trials and Mu Sigma Rho (the National Honorary Society for Statistics), and the Steering Committee of the Clinical Trials Transformation Initiative (CTTI). He is the Editor-in-Chief of CHANCE and Statistical Communications in Infectious Diseases (SCID). Dr. Evans is a Visiting Professor at the Department of Innovative Clinical Trials and Data Science at Osaka University in Japan.

Toshimitsu Hamasaki (Ph.D. in Mathematical Science from Osaka University) is the Director of Data Science at National Cerebral and Cardiovascular Center (NCVC), Osaka, Japan. He has been involved in biopharmaceutical statistics for over 20 years, and prior to joining NCVC, worked at Shiogoni, Pfizer Japan and Osaka University. He has been actively involved in biostatistical research, and is the author of more than 150 peer-reviewed publications and three textbooks on clinical trials including Group-Sequential Clinical Trials with Multiple Co-Objectives. Dr. Hamasaki was the member of ICH E5 Guideline Implementation Working Group as a representative of Japan Pharmaceutical Manufacturers Association to develop the Q & A document on the guideline. He currently serves as an Associate Editor for Statistics in Biopharmaceutical Research and Journal of Biopharmaceutical Statistics, and Editor for CHANCE. He is an elected member

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Weili He (Ph.D. in Biostatistics from University of Medicine and Dentistry, NJ) is the head of Global Medical Affairs Statistics, Data and Statistical Sciences at AbbVie. Prior to joining AbbVie, Weili worked in Clinical Biostatistics at Merck & Co., Inc. for over 20 years. Her research interests include survival and longitudinal data modeling, missing data imputation, cancer Phase I & II designs, repeated categorical data modeling, surrogate marker evaluations, adaptive design methodologies and implementations, methods for benefit-risk assessment, and methods utilizing real world evidence to augment clinical research and HTA assessment. Dr. She has published extensively in the areas of adaptive designs and benefit-risk evaluations, and is the author of more than 50 peer-reviewed publications in statistical and medical journals.

Shuyen Ho (Ph.D. in Statistics from University of Wisconsin-Madison) is a Statistical Sciences Director at UCB BioSciences in RTP, North Carolina. Shuyen has worked in the pharmaceutical industry for 27 years. Prior to UCB, he was a Biostatistics Director at Parexel, Clinical Statistics Director at GlaxoSmithKline (GSK) and Statistics Group Leader at Merck. He has extensive experience in Phase II & III clinical development and helped developed widely used respiratory medicines such as Claritin, Advair and Flonase-

Wei-Yin Loh (Ph.D. in Statistics from University of California, Berkeley) is Professor of Statistics at the University of Wisconsin, Madison. He is a Fellow of the American Statistical Association and the Institute of Mathematical Statistics and a consultant to government and industry. He has been developing classification and regression tree algorithms for more than thirty years. See http://www.stat.wisc.edu/~loh/.

Guanghan Frank Liu (Ph.D. in Statistics from University of California, Los Angeles) is a distinguished scientist at Merck & Co. Inc. For the past 20 years, he has worked in a variety of therapeutic areas, including neuroscience, psychiatry, infectious disease, and vaccines. His research interests include methods for longitudinal trials, missing data, safety analysis, and noninferiority trials. Frank is a Fellow of ASA, and an associate editor for Journal of Biopharmaceutical Statistics and for Statistics in Biosciences. He also co-led a Bayesian missing data analysis sub-team in the DIA Bayesian Working Groups.

Frank Pétavy (M.Sc. in Statistics from Ecole Nationale de la Statistique et de l'Analyse de l'Information) is the head of Biostatistics and Methodology Support (ad interim) at the European Medicines Agency. His Office provides statistical and methodology support to the Agency's key processes for the development and evaluation of medicines, and actively collaborates with statisticians of EU national medicines agencies within the CHMP Biostatistics Working Party, including the development of methodology guidelines. As an EU representative, he is a member of the ICH E9(R1) Expert Working Group that is drafting the Addendum on estimands and sensitivity analysis in clinical trials. Before the EMA, Frank held several statistical positions over 14 years in the pharmaceutical industry (IPSEN, GSK, Amgen), covering all aspects of drug development from compound selection to post-marketing trials, in Spain and the UK.

Krishan Singh (Ph.D. in Biostatistics from Medical University of South Carolina) has been working in the pharmaceutical industry for 29 years, starting at Smith Kline & French which subsequently became GlaxoSmithKline following mergers/acquisitions. In his 29 years in the industry as a statistician, he has supported the clinical development of drugs across a number of therapeutic areas leading to successful regulatory submissions and market authorization of six new drugs in cardiovascular, inflammation and tissue repair, anti-infectives, respiratory and rare diseases. He is currently a member of the ASA Safety Monitoring Working group. Krishan brings extensive experience in the application of statistical methodologies for the evaluation of safety and efficacy of investigational drugs.

Andrew Thomson (Ph.D. in Statistics from London School of Hygiene and Tropical Medicine) is a statistician at the EMA Office of Biostatistics and Methodology Support, joining in 2014. He supports the methodological aspects of the assessments of Marketing Authorizations Applications, as well as Scientific Advice, and methodological aspects of Pediatric Investigational Plans. He has worked extensively on the methodological aspects of the EMA Reflection Paper on the use of extrapolation of efficacy in pediatric studies. Prior to the EMA, he worked at the UK regulator, the Medicines and Healthcare Product Regulatory Agency. Here he worked initially as a statistical assessor in the Licensing Division, assessing Marketing Application Authorizations and providing Scientific Advice to companies. After rising to Senior Statistical Assessor, he moved to the Vigilance and Risk Management of Medicines Division, to be Head of Epidemiology.

Naitee Ting (Ph.D. in Statistics from Colorado State University) is a Fellow of American Statistical Association (ASA). He is currently a Director in the Department of Biostatistics and Data Sciences at Boehringer-Ingelheim Pharmaceuticals Inc. (BI). He joined BI in September of 2009, and before joining BI, he was at Pfizer Inc. for 22 years (1987-2009). Naitee published articles in Technometrics, Statistics in Medicine, Drug Information Journal, Journal of Statistical Planning and Inference, Journal of Biopharmaceutical Statistics, Biometrical Journal, Statistics and Probability Letters, and Journal of Statistical Computation and Simulation. His book "Dose Finding in Drug Development" was published in 2006 by Springer, and is considered as the leading reference in the field of dose response clinical trials. Naitee is an adjunct professor of Columbia University, and the University of Connecticut. Naitee has been an active member of both the ASA and the International Chinese Statistical Association (ICSA).

Ram C. Tiwari (Ph.D. in Mathematical Statistics from Florida State University) is the Director for Division of Biostatistics, CDRH, effective June 27, 2016. He joined FDA in April 2008 as Associate Director for Statistical Science and Policy in the Immediate Office, Office of Biostatistics, Office of Translational Sciences, CDER. Prior to joining FDA, he served as Program Director at National Cancer Institute, NIH, and as Professor and Chair, Department of Mathematics, University of North Carolina at Charlotte. He has published 200+ research papers on a wide range of statistical topics. His current research interests include developing frequentist and Bayesian methods in clinical trials and pre-and-post market drug/device safety evaluation.

Guei-Feng Tsai (Ph.D. in Statistics from Oregon State University) is currently a statistical team leader at Division of New Drugs, Center for Drug Evaluation (CDE), Taiwan. The team supports all statistical aspects of regulatory submissions and consultation services in drugs and medical devices. She has worked in CDE for over 10 years. Prior to joining CDE, she served as a postdoctoral fellow in the Department of Statistics at Northwestern University.

William (Bill) Wang is an executive director, clinical safety statistics, in the department of Biostatistics and Research Decision Sciences (BARDS), Merck Research Laboratories. He has over 20 years of experience in the pharmaceutical industry, with expertise and research publications in statistical design, analysis, clinical data management and their technology enablement. During his 15-year tenure at Merck, he supported regulatory filings in multiple therapeutic areas and established the BARDS Asia Pacific operation. Since 2010, he has served on the DIA China Regional Advisory Board and the DIA's Global Community Leadership Council (CLC), including the chairmanship of the DIA China Statistics Community. He was a recipient of the DIA global inspire award in 2012.

Naiqing Zhao, (Master's in Biostatistics from University of Newcastle, Australia) Professor, Department of Biostatistics, School of Public Health, Fudan University, China. Prof. Zhao's experience spans from the design and analysis of clinical trials, clinical epidemiology, biological signaling, to statistical methodology research in biomedical field. He has been teaching biostatistics for over 20 years and serving as an external review expert of clinical trial statistics for the China Food and Drug Administration for more than a decade.

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Registration Fees for Conference Tutorials

	Payment must be made or check must be mailed on or before			
	October 1	November 1	December 1	Onsite
Three Days Conference	$770	$900	$1050	$1150
One Day Conference (Monday, Tuesday, or Wednesday)	$425	$480	$530	$610
Retiree/Student (Proof of status needed)	$375	$425	$475	$575
Speakers Dinner(Optional, Monday 7:00 pm)	$50	$60	$60	$60
Bound proceedings, which include handouts for all tutorials, will be provided to all attendees.				

Registration Fees for Short Courses

Two 2-day short courses will be offered on December 07 and December 08 after the tutorial sessions. Registration for the short courses is needed. The registration for a course is independent of the registration for the tutorial sessions. The registration fee covers the text book used in the short course.

	Payment must be made or check must be mailed on or before			
	October 1	November 1	December 1	Later or On site
Course 1	$1010	$1130	$1,180	$1250
Course 2 (includes text book)	$1010	$1130	$1,180	$1250

The following books will be used and sold during the conference. Please order the books through the registration page. You should not order the book used for the short course you registered unless you want to order extra copies.

Book Information (Author, Title, etc.)	**Price (USD)**	
	List	**Discount**
Springer		
Naitee Ting, Ding-Geng Chen, Shuyen Ho, and Joseph C. Cappelleri, *Phase II Clinical Development of New Drugs* (1 st Edition), 2017, 250 Pages, ISBN: 978-981-10-4194-5	109	68
Hamasaki, T., Evans, S.R.Asakura, K., and Ochiai, T., , *Group-Sequential Clinical Trials with Multiple Co-Objectives* (1st Edition), 2016, 110 Pages, ISBN: 978-4-431-55900-9	54.99	36
Sozu, T., Sugimoto, T., Hamasaki, T., and Evans, S.R., *Sample Size Determination in Clinical Trials with Multiple Endpoints* (1st Edition), 2015, 80 Pages, ISBN: 978-3-319-22005-5	69.99	45
John Wiley		
Alan Agresti, *Foundations of Linear and Generalized Linear Models* (1st Edition), 2015, 472 Pages, ISBN: 978-1-118-73003-4	125	74
Taylor and Francis		
Ding-Geng (Din) Chen, and Karl E. Peace, *Applied Meta-Analysis with R* (1st Edition), 2013, 342 Pages, ISBN: 9781466505995	97.95	62
Alex Dmitrienko, Ajit C. Tamhane, and Frank Bretz, *Multiple Testing Problems in Pharmaceutical Statistics* (1 st Edition), 2009, 320 Pages, ISBN: 9781584889847 **(Included in Short Course 2)**	99.95	63
Leo Breiman, Jerome Friedman, Charles J. Stone, and R.A. Olshen, *Classification and Regression Trees* (1 st Edition), 1984, 368 Pages, ISBN: 9780412048418 **(Recommended by instructors and included in Short Course 1)**	109.95	69

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Meeting facilities are in the Tropicana's Havana Tower state-of-the-art complex with 502 nonsmoking rooms where attendees stay in soundproof climate controlled rooms with direct-dial phones, cable color TV, coffee makers, hairdryers, refrigerators, safe, iron and board, complimentary wireless internet and gorgeous views of the Atlantic City skyline. Driving directions are on the last page.

- There is a guest check in desk on the 3rd floor of the Havana Tower and meeting facilities are on the 4th floor.
- It's one of the largest NJ hotels, with 2,079 rooms, elegant public areas, exclusive retail shops and fine dining.
- It's on the beach with a complimentary heated indoor pool on the sixth floor of the South Tower.
- It has free Wi-Fi in the rooms and conference floor. The casino is in a separate building connected by a bridge.
- The AtlantiCare Life Center fully equipped fitness facility is directly accessible from the Havana Tower for a fee of $10 per day for hotel guests.
- Free parking to the Deming conference attendees.

TRAVEL TO THE CONFERENCE

AIR: Check both Atlantic City (ACY) and Philadelphia (PHL) to search for the best fare and connections. The cheapest quick airport connection to PHL is the Tropiano shuttle, requiring reservations at least two days in advance at (215) 616-5370. It charges $55 from PHL directly to the Tropicana. A tip is expected. There is a $10 jitney from ACY as well as a $35 taxi service to the Tropicana. For both of these, call Ext 2002 from the Taxi and Shuttle Service Desk, located in the Baggage Claim Area, near the Exit door. You can also call 609-344-8642 or 609-576-2776 in advance**.** The cheapest connection from PHL is the below referenced SEPTA, but this will take more than two hours. One can rent a car (www.bnm.com) but it isn't necessary during one's stay. Also consider discount airlines not on the major search engines such as Spirit; AirTran, Frontier, and Southwest. While we don't recommend Newark Airport except as a means of saving money and perhaps travel time on international flights, there is a #67 NJ Transit bus (requiring a change at Toms River) as well as several train service options to Atlantic City, including the one referenced below.

RAIL: NJ Transit has relatively frequent local (14 daily trips with 6 stops) service to Philadelphia connecting with Amtrak, NJ Transit to NYC, and SEPTA at 30th Street and PATCO at Lindenwold. Free shuttle busses meet all trains and provide direct service to the Tropicana. www.njtransit.com/pdf/rail/R0090.pdf has a schedule that also shows the SEPTA connections from PHL to 30th Street. Direct service from NYC with a stop in Newark is available www.acestrain.com, Friday through Sunday only.

BUS: Call the Tropicana casino bus transportation department, (888) 275-1212 # 1 to find if there is service from your local neighborhood as some of these buses 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. Explore Greyhound, which has open return service with a slot play bonus from 13 cities www.luckystreakbus.com. While it has fewer trips, travel is easier than with the train as there are no transfers.

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, Route 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 Quarter" Garage (Havana Tower) is on your left, off Atlantic Avenue. Self or valet (doesn't permit easy access to your car during your stay) parking is $10 per stay for hotel guests with unlimited in and out privileges.

INFO: For general tourist info visit www.visitnj.org/city/atlantic-city 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 the foot of the Atlantic City Expressway or strolling on the Boardwalk to the pier shops at Caesars. Remember there is no sales tax on apparel in NJ.

MEALS: Take the time to explore www.tropicana.net. It contains complete details of the meeting facility and gives descriptions of the 22 restaurants and other attractions. We provide a full hot breakfast on Monday and a continental breakfast on Tuesday and Wednesday before our morning sessions as well as afternoon refreshment breaks. There is a subsidized Speaker Dinner on Monday and a free one-hour reception on Sunday with cold drinks, snacks, and a cash bar where you can meet with 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, complete rules, and background information are on the conference website. The application must be submitted after the conference and before April 1, 2018. The award will be announced and paid directly to the applicant on May 15, 2018. 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 Scholarship Committee, whose decision is final, reserves the right to distribute the amount of the scholarship to multiple recipients at their discretion.

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*** Walter R. Young has chaired the Deming Conference for forty-eight consecutive years.**