



Sino-American Pharmaceutical Professionals Association
-Greater Philadelphia Chapter
美中医药开发协会大费城分会

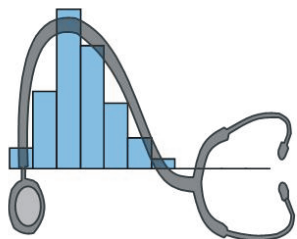


Biometrics: Clinical Trials and Beyond *Statistics , Programming, and Data Management in Research, Development, and Regulatory Submissions. **For all, Not Just Statisticians!***

Keynote Presentations

**Sue-Jane Wang, PhD, Associate Director, Adaptive Design and
Pharmacogenomics, CDER, FDA**
**Recent Advances and Challenges in Clinical Trials for Medical Product
Development**

Kevin Chartier, PhD, Franchise Head, Novartis
Transforming from a Statistician to a Drug Developer/Researcher



Fred Yang, PhD
Head of Biostatistics and Data Science
Alternative Development Program
GSK

Saturday, November 6, 2010
Holiday Inn Hotel & Conference Center

432 West Pennsylvania Ave., Fort Washington, PA 19034

Conference Co-Chairs:

Yonggang Zhao, PhD, MBA
Associate Director
Oncology Business Unit
Pfizer

This **SAPA-GP Biometrics Conference** is a one day event, which provides a comprehensive overview of statistical and quantitative applications in medical research and drug development. The conference is targeted for pharmaceutical R&D scientists, clinicians, statisticians, market researchers, and anyone else (especially graduate students) who are interested in gaining a better understanding of the role of biometrics in pharmaceutical and biotech industry. Experts from the agency, industry, and academia will discuss the following areas:

- **Strategic roles of statistics in drug development**
- **Statistics in clinical and non-clinical (discovery, basic research, biomarker and manufacturing)**
- **Statistics in pharmaceutical, biotech, and CRO**
- **Data management, programming, standardization, and submission**
- **Recent advances and challenges**



To register, please logon to SAPA-GP website

www.sapa-gp.org

Questions? Please email: yonggang.zhao@pfizer.com



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Agenda

8:00-8:45 **Registration**

Morning Session

Moderator: Fred Yang, PhD

8:45-8:50 **Welcome and Opening Remarks**

Jingsong Wang, MD, SAPA-GP president
Director, Discovery Medicine & Clinical Pharmacology, BMS
Adjunct Assistant Professor of Medicine, University of Pennsylvania

8:50-9:00 **Program Introduction**

Fred Yang, PhD
Head, Biostatistics and Data Science, Alternative Development Program, GSK

9:00-9:45 **Keynote Presentation**

Transforming from a Statistician to a Drug Developer/Researcher

Kevin Chartier, PhD
Franchise Head, Novartis

9:45-10:15 **Statistics in Clinical Trials for Drug and Vaccine Development**

Ivan Chan, PhD
Senior Director, Clinical Biostatistics, Merck

10:15-10:45 **Coffee Break & Networking**

10:45-11:15 **Perspectives of Nonclinical Statistics in Biotech Drug Research & Development**

Bill Pikounis, PhD
Director, Nonclinical Statistics, Johnson & Johnson

11:15-12:00 **Keynote Presentation**

Recent Advances and Challenges in Clinical Trials for Medical Product Development

Sue-Jane Wang, PhD
Associate Director, Adaptive Design and Pharmacogenomics
Office of Biostatistics, Office of Translational Sciences, CDER, FDA

12:00-1:00 **Lunch** (on-site lunch is provided free for all attendees)

Afternoon Session

Moderator: Yonggang Zhao, PhD, MBA

1:00-1:30 **Large Scale Data Analysis: From Hypotheses Testing to Effect Size Estimation**

Jason Liao, PhD
Professor and Director, Biostatistics Core, Penn State Cancer Institute

1:30-2:00 **Real-World Examples Where Statisticians Play a Key Role**

Jonathan Ma, PhD
President and CEO, Mason StatConsulting

2:00-2:30 **Clinical Data Management and Standardization**

Peter Cheng, PhD
Principal, Clinical Data Management, Accenture/Pfizer

2:30 -3:00 **Coffee Break & Networking**

3:00-3:30 **Managing Statistical Programming for Regulatory Submission**

Simon Lin, PhD
Director, Global Biostatistics Analysis and Programming, Oncology PCU, Eisai Inc

3:30-4:00 **Challenges and Opportunities in CRO Business (US and China)**

Xin Ke, PhD
President, K&L Consulting Services

4:00 **Concluding remarks and adjourn**

Speaker Biographies (Listed Alphabetically)



Ivan Chan, PhD

Dr. Ivan Chan received M.S. in Statistics from The Chinese University of Hong Kong in 1991 and Ph.D. in Biostatistics from University of Minnesota, United States in 1995. He joined Merck Research Laboratories in 1995 as a statistician supporting vaccine research. Currently Dr. Chan is Senior Director of Late Development Statistics, and he heads the statistics group supporting all vaccine clinical research programs at Merck. He is also active in promoting diversity at Merck and helping organize diversity leadership training programs. Professionally, Dr. Chan is active in multitudes of activities. He serves as Associate Editor for *Biometrics*, *Journal of Biopharmaceutical Statistics*, and *Statistics in Biosciences*. Dr. Chan is the president-elect of the International Chinese Statistical Association (ICSA) and the Executive Director for the International Society for Biopharmaceutical Statistics (ISBS). He also serves as a core member on a Clinical Trial Review Committee of the National Institutes of Health (NIH) and an external advisor to the University of Hong Kong. Dr. Chan has chaired/co-chaired several national/international scientific conferences including the annual meeting of the Society For Clinical Trials, ISBS symposium in China, and the FDA Industry Statistics Workshop. Dr. Chan has 50+ publications in statistical and clinical journals.

Kevin Chartier, PhD

Kevin Chartier is Global Franchise Head, Respiratory and Established Medicines Franchises at Novartis. Prior to this, Kevin was Assistant Vice President and Site Head of Global Biostatistics & Programming at legacy-Wyeth's Research & Development Headquarters. Kevin has held positions of increasing responsibility in Research & Development as Sr. Director and Global Advisor supporting worldwide regulatory submissions in several therapeutic areas including Cardiovascular and Neuroscience. Kevin's has a Ph.D. and M.S. in Statistics from Kansas State University and B.S. in Mathematics.



Peter Cheng, PhD

Peter Cheng has worked over 10 years with clinical trial management, database design, data validation/derivation programming and clinical programming in pharmaceutical industry. He has extensive experience with SDTM/CDISC implementation and supervises an off-shore team to map clinical data from clients' in-house format to this standard. He has supported various therapeutic areas in musculoskeletal, neuroscience, oncology and inflammation. He has been a core team member to design and develop over 40 Data Standard Packages for the global neuroscience data. He received his Ph. D degree in computational chemistry from Boston College.



Xin Ke, PhD

Dr. Xin Ke is the founder and President of K&L Consulting Services, Inc., a CRO company founded in 1995 based in Pennsylvania supplying services in biostatistics, data management, programming, and e-Submission for Phase I to IV clinical trial studies and agency submission. Prior to "K&L", Xin held multiple positions either as a consultant or an employee in multiple pharmaceutical companies such as Ciba-Geigy (later became Novartis), PRI- Johnson&Johnson (later became PRD-Johnson&Johnson), Sanofi (became Sanofi-Aventis), GSK, Astra-Merck (became AstraZeneca), and Merck. Currently Xin is leading "K&L" supplying services to multiple pharmaceuticals in US. In 2009, Xin co-founded Nanjing LiDa Medical Research & Development Co. in China to supply Statistics, Data Management, Programming, Medical Writing and e-Submission services to world-wide international pharmaceutical companies in China. Dr. Xin Ke received his B.S degree in Applied Mathematics from Tsinghua University (1982), and his Ph.D degree in Applied Mathematics from Rutgers University.

Jason Liao, PhD

Jason Liao got his MS degree from Chinese Academy of Preventive Medicine, Beijing, in 1986 and Ph.D. from Johns Hopkins University in 1993. He has taught in five universities in the United States. In his current position, he oversees the biostatistical operation in Penn State Hershey Cancer Institute ranging from basic science to clinical trials. His methodological interests include categorical data, statistical computing and simulation, mixed effects model and longitudinal data, large scale data, cancer risk modeling and prediction.



Simon Lin, PhD

Simon has been leading all Biostat programming efforts in the oncology area for Eisai. He also managed programming activities in the Frontier PCU and safety programming activities in the Premier PCU. He has been a key driver and contributor towards Eisai's initiative to develop the Standard Reporting Systems. Simon has extensive submission and CRO management experiences in broad therapeutic areas. He has had previous programming and analytic experiences in the pharmaceutical industry, as well as other highly technical organizations. He received his Ph.D from Peking University and earned his Post-Docs from the University of British Columbia.

Jonathan Ma, PhD, MBA

Dr. Ma has over 15 years of combined experiences with the FDA, industry and CRO/consulting across multiple therapeutic areas. Dr. Ma previously worked for Pfizer as an associate director of biometrics at Pfizer's New York City headquarters supporting Lipitor's post-marketing Phase 3b/4 programs. Dr. Ma also used to work for the Center for Drug Evaluation and Research (CDER)/FDA to review new drug applications (NDAs and INDs) across multiple therapeutic areas. In early 2004, Dr. Ma founded an independent consulting business – Mason StatConsulting, which provides statistical consulting services to pharma/biotech clients on various projects. Dr. Ma is frequently asked to provide consultations on regulatory strategies and represent clients to attend FDA/SFDA meetings. Dr. Ma had an adjunct assistant professorship of statistics at Columbia University. He is a council member of the Gerson Lehrman Group where he is regularly invited to provide consultations to investment groups and law firms. Dr. Ma received a PhD in Biostatistics from Yale University, a BS in Mathematics from Beijing University (China) and an MBA from Columbia Business School.



Bill Pikounis, PhD

Bill Pikounis joined Johnson & Johnson in January 2005 when a dedicated Nonclinical Statistics group was created at Centocor to serve needs across discovery, basic research, development, and product formulations of biologic, large molecule products. Previously Bill was at Merck in preclinical and nonclinical statistics, after receiving his Ph.D. from the University of Florida in 1991. Bill has served as president of the Princeton-Trenton chapter of the American Statistical Association (ASA) and the Philadelphia Chapter of the ASA. His professional interests lie in data graphs, resampling methods, resistance & robustness, longitudinal data analysis, statistical computing, and software solutions. For more details see <http://billpikounis.net/>.

Sue-Jane Wang, PhD

Dr. Sue-Jane Wang is presently Associate Director for Adaptive Design and Pharmacogenomics, Office of Biostatistics, Office of Translational Sciences, Center for Drug Evaluation and Research, U.S. Food and Drug Administration.

Dr. Wang has made significant contributions to the regulatory and clinical sciences of U.S. FDA, particularly to set expectations for the quality and efficiency of regulatory decision making about pharmacogenomics and adaptive design clinical trials. As a result, Dr. Wang received the FDA level individual scientific achievement award on excellence in analytical science this June. The award acknowledged her for a sustained record of published regulatory research in statistical design and methodology advancing complex and emerging clinical trial designs and analysis that support regulatory guidance, policies and review. She is the first researcher as a biostatistical scientist in Drug Center receiving FDA level individual scientific achievement award.

Over the last five years, Dr. Wang has represented US FDA to participate in the international conferences in addition to domestic conferences. Dr. Wang's recent research interests have focused on issues in the adaptive design and pharmacogenomics.

She has published more than 70 peer reviewed papers in statistical, medical, genomics, and bioinformatics journals. She serves as Associate Editor of Statistics in Medicine and of Statistics in BioSciences. Dr. Wang is a faculty at Johns Hopkins University and an elected member of the International Statistical Institute. She has served as an Editor-in-Chief of Journal of Pharmaceutical Statistics. She is the conference co-chair for the upcoming MCP conference in 2011.

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