



Sino-American Pharmaceutical Professionals Association
Clinical Biostatistics and Programming Symposium

Sino-American Pharmaceutical Professionals Association
Clinical Biostatistics and Programming
Symposium

University of Medicine and Dentistry of New Jersey
675 Hoes Lane West
Piscataway, NJ 08854-5635

November 19, 2011



Sino-American Pharmaceutical Professionals Association **Clinical Biostatistics and Programming Symposium**

Symposium Program Committee Co-Chairs

Len Oppenheimer, Ph.D., Janssen Pharmaceutical Companies of Johnson & Johnson
Mei Wu, Sanofi

Symposium Program Committee

Jaishri Alladi, Cynthia He, Gordon Lan, Junfang Li
Zhaoling Meng, Denis Michel, Ing-Ming Pan, Cindy Song, Li Joy Wang

Registration and Breakfast (8:00 AM to 8:45 AM)

Morning Session (8:45 AM to 12:15PM)

8:45 AM – 9:05 AM

Opening Remarks

Baoguo Huang, Ph.D.
SAPA President

9:05 AM – 9:20 AM

Welcome and Meeting Agenda

Len Oppenheimer, Ph.D., Symposium Co-Chair
Janssen Pharmaceutical Companies of Johnson & Johnson

9:20 AM – 12:15 PM

Plenary Session

Session Chair: Len Oppenheimer / Mei Wu

9:20 AM – 10:00 AM

Data Standards, Statisticians, Programmers and Review: Change, Transparency and Collaboration

Stephen E. Wilson, Dr.P.H., Capt. USPHS
Director, Division of Biometrics III, CDER, FDA

10:00 AM – 10:40 AM

CDISC 2011 and Beyond

Stephen Kopko
CDISC

10:40 AM – 10:55 AM

Coffee Break

10:55 AM – 11:35 AM

Frameworks, Guidelines and Methodologies: What is new in benefit-risk assessment?



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Clinical Biostatistics and Programming Symposium

Bennett Levitan, M.D.-Ph.D.
Director, Quantitative Safety Research, Department of Epidemiology
Janssen Pharmaceutical Companies of Johnson & Johnson

11:35 AM – 12:15 PM **Statistical Procedures: From Theory to Practice**
Kuang-Kuo Gordon Lan, Ph.D.
Senior Director, Quantitative Decision Strategy
Janssen Pharmaceutical Companies of Johnson & Johnson

Lunch
(12:15 PM to 1:15 PM)

Afternoon Session
(1:15 PM to 5:00 PM)

1:15 PM – 3:00 PM Parallel Sessions

Biostatistics <u>Session Chair: Zhaoling Meng</u>	Clinical Programming <u>Session Chair: Denis Michel</u>
1:15 PM - 1:40 PM An Overview of Multi-Regional Clinical Trials with Emphasis on Issues of Concern to Statisticians Bruce Binkowitz, Ph.D. Senior Director, Late Development Statistics Merck Research Laboratories (MRL)	1:15 PM - 1:40 PM SDTM Metadata Submission – How to Avoid Common Mistakes Carol Vaughn Manager, Global Projects Support, Biostatistics and Programming Sanofi
1:40 PM - 2:05 PM Points-to-consider for Assessment of Consistency of Treatment Effects in Multi-regional Clinical Trials. Hui Quan, Ph.D. Senior Director, Biostatistics and Programming Sanofi	1:40 PM - 2:00 PM CDISC SDTM and ADaM: Lessons Learned from Submission Work Li Joy Wang Director, Head of Statistical Programming Celgene Corporation
2:05 PM - 2:30 PM The Totality of Evidence in Safety and Efficacy Evaluation of Medical Products Greg Soon, Ph.D. Lead Math Statistician	2:00 PM - 2:20 PM Evaluation of Drug Induced Serious Hepatotoxicity (eDISH) Ing-Ming Pan Director, Programming Janssen Pharmaceutical Companies of Johnson & Johnson



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<p>FDA</p> <p>2:30 PM - 2:55 PM</p> <p>Integrated vs. Disintegrated Summary of Effectiveness and Safety</p> <p>Kao-Tai Tsai, Ph.D. Director, Department of Biostatistics & Programming Celgene Corporation</p> <p>2:55 PM - 3:00 PM</p> <p>Q & A</p>	<p>2:20 PM – 2:40 PM</p> <p>Clinical Registries - What Biostatisticians and Programmers Need to Know</p> <p>Sherry Meeh Senior Manager, Programming Janssen Pharmaceutical Companies of Johnson & Johnson</p> <p>2:40 PM – 3:00 PM</p> <p>ClinicalTrials.gov Result Posting - Automation with Flexibility</p> <p>Eric Sun Senior Manager, Solution Leader Sanofi</p>
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3:00 PM – 3:15 PM

Coffee Break

3:15 PM – 4:45 PM

Panel Discussion

Session Chair: Barry Schwab, Ph.D.

(Introduction by Ing-Ming Pan)

**Operating in a Global Environment for Biostatistics and Programming:
Current Trends and Future Directions**

Moderator

Barry Schwab, Ph.D.

Vice President

Clinical Biostatistics Head – Neuroscience and Established Products
Janssen Pharmaceutical Companies of Johnson & Johnson

Panelists

Raymond P. Bain, Ph.D.

Vice President

Biostatistics and Research Decision Sciences (BARDS)
Global Clinical Development and Regulatory Affairs (GCDRA)
Merck Research Laboratories (MRL)

Kimberly DeWoody, Ph.D.

Global Head, Biostatistics & Programming

Janssen Pharmaceutical Companies of Johnson & Johnson



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Dominic Labriola, Ph.D.

Vice President, Global Biometric Sciences
Bristol-Myers Squibb Company

C. S. Wayne Weng, Ph.D.

Senior Director, Biostatistics & Statistical Programming
Novo Nordisk Inc., Princeton, New Jersey

Mei Wu

Head of global programming
Biostatistics and Programming
Sanofi

Irene Zhang

President/CEO
Everest Clinical Research Services Inc.

4:45 PM – 4:50 PM

Concluding Remarks

Mei Wu, Symposium Co-Chair
Sanofi

4:50 – 5:30 PM

**Presentation by Yantai Economic & Technological
Development Area**

Symposium Organizing Committee

Bao, Zhenhong (Charles); Chen, Kevin; Chen, Jiwen; Ding, Wei; Feng, Haixia (Helena);
Fu, Xuan (Helen); Gan, Frank; He, Handan; Huang, Baoguo; Li, Cai; Li, Xing;
Pu, Su-Fen; Tan, Qiang (John); Wang, Wenyan; Zhang Xiaoying



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Plenary Session

Session Chairs: Len Oppenheimer, Janssen Pharmaceutical Companies of Johnson & Johnson / Mei Wu, Sanofi

Data Standards, Statisticians, Programmers and Review: Change, Transparency and Collaboration

Stephen E. Wilson, Dr.P.H, Capt. USPHS, Director, Division of Biometrics III, CDER, FDA

Abstract:

21st Century Review is here! When a sponsor submits an NDA or a BLA to the Center for Drug Evaluation and Research (CDER), it needs to be complete and “review ready” on “Day 1.” For this to happen, all of the people who handle the data (data managers, programmers, statisticians, investigators, clinical trial monitors, reviewers, etc.), need to be working as a team to assure the quality, clarity and completeness of each and every submission.

Data standards, transparency and collaboration are key elements in what we are attempting to achieve in improving our abilities to make the important decisions associated with the review of new medical products. This talk will describe CDER’s plans for developing a standards-based review environment, with an emphasis on what industry programmers and statisticians need to be doing to help us all be successful. This is an opportunity to learn more about CDER’s progress and to think about how you can effectively contribute ... working with us to “get there.”

Biography:

Dr. Wilson has worked as a Statistical Reviewer and Supervisory Mathematical Statistician in FDA’s Center for Drug Evaluation and Research (CDER) for more than 24 years and is currently the Director of the Division of Biometrics III. He received his doctorate in Biostatistics from the University of North Carolina, Chapel Hill, in 1984.

Steve’s professional experience includes statistical research / management positions with the East West Center in Hawaii, the Indonesian Central Bureau of Statistics (Biro Pusat Statistik), the University of North Carolina, the Federated States of Micronesia and the World Bank. His professional interests and activities are currently focused on issues related to the development of data standards, improvements in



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clinical trials science and practice, review of new pharmaceutical products and the application of new technology and processes in the regulatory environment.

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CDISC 2011 and Beyond

Stephen Kopko, CDISC

Abstract:

Talk will give a brief introduction to CDISC, how and why the organization was formed, our mission, where we are today, what standards are available for use, how to gain access to all the documentation, interactions with FDA and other regulatory authorities as well as what the 1-5 year CDISC Roadmap holds for future standards development.

Biography:

Steve is currently a Submission Data Standards Consultant with CDISC working on the following CDISC Data Standards projects: Alzheimer's disease, Parkinson's disease, Polycystic Kidney Disease, Pain & Analgesia, and the FDA Legacy Data Conversion – Diabetes. Prior to this, Steve spent 34 years working in the Pharmaceutical industry at Pfizer (Legacy Wyeth), R. W. Johnson Pharm. Research Institute, SmithKline Beecham and McNeil Pharmaceutical in the areas of Statistical Programming, Data Management and Information Systems. Steve has been a member of the Drug Information Association for over 30 years. He served as a presenter, session chairperson, and program chairperson for a number of Clinical Data Management Workshops and Symposiums and the DIA Annual Meetings. He is a former member of the PhRMA/FDA Electronic Regulatory Submissions Working Group, which provided input to the ICH initiatives on performing electronic review of regulatory submissions. He was the Wyeth CDISC Industry Advisory Board representative in March 2005 and chaired the CDISC Advisory Board from 2008 to 2009. He led the CDISC standards implementation within Wyeth Research. Based on his background and experience in the industry, he understands and appreciates what standards can do for the industry. He recognizes the importance of close collaboration among all parties interested in standards for clinical trials research.

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Frameworks, Guidelines and Methodologies: What is new in benefit-risk assessment?

Bennett Levitan, M.D.-Ph.D., Director, Quantitative Safety Research, Department of Epidemiology, Janssen Pharmaceutical Companies of Johnson & Johnson

Abstracts:

Pharmaceutical companies are increasingly pressed to demonstrate not simply efficacy and safety of their products, but a superior benefit-risk profile compared to alternative treatments. The increased pressure for these benefit-risk assessments is made all the more difficult by the lack of any regulatory standards or approved approaches to performing them. The variety of safety endpoints, with varying timescales and degree of impact on



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patients, makes quantitative approaches difficult. As a result, efficacy and safety results from clinical studies are often reported separately, and benefit-risk is often only characterized qualitatively. To address these issues, a number of industry and regulatory organizations, including the FDA, EMA and PhRMA, have ongoing projects to develop standardized approaches towards benefit-risk assessment. This presentation will present an overview of these projects as well as touch upon some of the technical approaches used for quantitative benefit-risk assessment.

Biography:

Bennett Levitan, MD-PhD is Director, Quantitative Safety Research, Department of Epidemiology at Johnson & Johnson Pharmaceutical Research and Development. Dr. Levitan has over 20 years experience in decision analysis, modeling and simulation in both consulting and pharmaceuticals. He specializes in pharmaceutical benefit-risk assessment and is a frequent speaker at meetings on the topic. Bennett is currently co-leading technical development of the PhRMA Benefit Risk Action Team (BRAT) Framework for drug benefit-risk assessment. Bennett is also a member of the Next Steps Working Group, a public-private group focused on methods and collaboration for pharmaceutical benefit-risk assessment. Bennett received his B.Sc. (Electrical Engineering) from Columbia University in New York and his M.D.-Ph.D. (Bioengineering) from the University of Pennsylvania. He worked as a postdoctoral fellow at the Santa Fe Institute. His research and consulting work have dealt with pharmaceutical benefit-risk assessment, organizational learning, evolutionary-based optimization, high-dimensional data visualization, and combinatorial chemistry.

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Statistical Procedures: From Theory to Practice

Kuang-Kuo Gordon Lan, Ph.D., Senior Director, Quantitative Decision Strategy, Janssen Pharmaceutical Companies of Johnson & Johnson

Abstracts:

There is always a big gap between the development of a statistical procedure and its implementation in practice. In this talk, I will cover two interesting examples:

1. The field of statistical sequential analysis was founded by Abraham Wald in the 1940's. The most notable procedure, the sequential probability ratio test (SPRT), was originally developed for quality control. Currently, it is also the predominant method for classifying examinees in a variable-length computerized classification test. I will elaborate on the difference between open and closed sequential procedures, and explain why SPRT cannot be applied directly to clinical trials for drug development due to this difference.



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- 2. The definition of the treatment effect in a clinical trial protocol depends on an ANCOVA model, yet the model itself is often difficult to specify correctly in advance. In other words, it is not clear to us how to use ANCOVA appropriately in drug development, yet we often act as if we do.

Biography:

Gordon Lan received his Ph.D. in Mathematical Statistics from Columbia University in 1974. Before joining Johnson & Johnson in 2005, he held positions as Mathematical Statistician at the National Heart, Lung and Blood Institute (NHLBI/NIH), Professor of Statistics at George Washington University, Distinguished Scientist at Pfizer, and Statistics Fellow at Sanofi-Aventis.

Gordon has published more than 50 research papers on statistical methods in medical research and has given more than 200 invited talks at universities and professional meetings worldwide. Gordon was elected Fellow of the American Statistical Association in 1992, and Fellow of the Society of Clinical Trials in 2009.

Biostatistics

Session Chair: Zhaoling Meng, Sanofi

An Overview of Multi-Regional Clinical Trials with Emphasis on Issues of Concern to Statisticians

Bruce Binkowitz, Ph.D., Senior Director, Late Development Statistics, Merck Research Laboratories (MRL)

Abstract:

Clinical trials composed of investigator sites from across multiple regions of the world have become common practice. These multi-regional clinical trials (MRCTs) have benefits but also come with a set of challenges. Such large-scale clinical trials, conducted on a global scale, can be the basis for regulatory approval of new drug therapies. While these trials offer access to broad, diverse patient populations, they are not without logistical challenges. These challenges can result in significant debate during the regulatory decision-making process. In 2008, PhRMA sanctioned a Key Issue Team (KIT) to examine some of the issues surrounding MRCTs and propose recommendations. The KIT focused on issues surrounding: consistency of regional effects including statistical methods for assessment and case studies; a survey of PhRMA companies regarding operational practices surrounding MRCTs; points to



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consider when defining "region", including research of how regional effects were handled at FDA advisory committees; and issues arising when conducting MRCTs but the relevant regulatory guidances differ on what the key endpoints, timepoints, etc. should be. This presentation will provide an overview of selected topics from the recent PhRMA White Papers on the topic of MRCT, published in the September 2011 Drug Information Journal, with emphasis on topics that impact on, and can be influenced by, statisticians.

Biography:

Dr. Binkowitz is Senior Director of Late Development Statistics (LDS) currently overseeing all aspects of LDS involvement in cardiovascular research. Dr. Binkowitz has over 25 years of experience in the Pharmaceutical Industry involving the design, analysis, and strategy of projects across many different therapeutic areas. Dr. Binkowitz has extensive experience in interacting with health authorities worldwide, and his favorite areas of research emphasize the applications of Statistics in a regulatory environment. Towards this idea, Dr. Binkowitz is currently co-chair of the PhRMA Multi-Regional Clinical Trial Key Issue Team.

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Points-to-consider for Assessment of Consistency of Treatment Effects in Multi-regional Clinical Trials

Hui Quan, Ph.D., Senior Director, Biostatistics and Programming, Sanofi

Abstract:

Multi-regional clinical trials (MRCTs) have been widely used for efficient global new drug developments. One major challenge for MRCT design and analysis is the assessment of consistency of treatment effects across regions. In this presentation, methods for consistency assessment will be summarized. Computational results will be provided to illustrate potential issues associated with some of the methods. A multinational trial example with a time-to-event endpoint will be used to demonstrate the application of the methods.

Biography:

Hui Quan is currently a senior director at the Biostatistics and Programming Department of Sanofi and is an adjunct associate professor at UMDNJ. He obtained his PhD degree in statistics from Columbia University in 1990. He has 67 publications including 43 statistical papers in peer reviewed journals. He serves as an associate editor for Statistics in Biopharmaceutical Research and is an elected ASA fellow.

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The Totality of Evidence in Safety and Efficacy Evaluation of Medical Products

Greg Soon, Ph.D., Lead Math Statistician, FDA

Abstract:

TBD

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Integrated vs. Disintegrated Summary of Effectiveness and Safety

Kao-Tai Tsai, Ph.D., Director, Department of Biostatistics & Programming, Celgene Corporation

Abstract:

As stated by R. Peto that there is simply no serious scientific alternative to the generation of large scale randomized evidence for the planning of health care throughout the world. Furthermore, R. Temple of the FDA indicated that ISS represents a revolution in our approach to safety assessment and we almost have to look at safety as an integrated analysis of all data.

Quite often in our industrial practice, large volume of tables are compiled for the ISS/ISE report with disproportional amount of useful information. In this presentation, we will show how one can take advantage of the large integrated data to better understand the treatment effect profile on both safety and efficacy, in addition to the identification of subgroups of patients for the potentially beneficial individualized therapies. An integrated clinical trial database will be used to illustrate the implementation of these methodologies.

Biography:

Kao-Tai Tsai obtained his Ph.D. in Mathematical Statistics from University of California, San Diego and had worked at AT&T Bell Laboratories to conduct statistical research, modeling, and exploratory data analysis. After that, he joined the US FDA and later pharmaceutical companies to focus on biostatistics, clinical trial research and data analysis to address the unmet needs in human health. He has been quite active in statistical profession and had engaged in numerous invited lectures, short courses, presentations and seminars on practical statistical issues related to clinical trials. In addition, he had also served as President of the NJ chapter of the ASA, member of the Board of Directors and various committees of ICSA, and symposium organizers for several professional organizations. His recent research includes topics in clinical trials and applications of statistical graphics in data analysis.

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Clinical Programming

Session Chair: Denis Michel, Janssen Pharmaceutical Companies of Johnson & Johnson



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SDTM Metadata Submission - How to Avoid Common Mistakes

Carol Vaughn, Manager, Global Projects Support, Biostatistics and Programming, Sanofi

Abstract:

CDISC will soon make public the "SDTM Metadata Submission Guidelines". The main focus of this document will be on acceptable practices and formats for preparation of the define.xml (the metadata which describes the structure and content of the SDTM datasets). For years the pharmaceutical industry has been struggling to prepare compliant define.xml without such a central source of instructions. Not surprisingly, misunderstanding was common and many mistakes have been made. This presentation will cover the most common mistakes and provide information for the correct preparation.

Biography:

Carol has worked in the pharmaceutical industry for 15 years. She was a statistical programmer for 12 years and then transitioned into the area of data standards. She presently serves as the US Biostatistics submission data standards specialist for Sanofi. She is an active member of the CDISC SDTM team as well as several sub-teams including the SDTM Metadata Submission Guidelines sub-team.

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CDISC SDTM and ADaM: Lessons Learned from Submission Work

Li Joy Wang, Director, Head of Statistical Programming, Celgene Corporation

Abstract:

Since regulatory submission according to CDISC standard is becoming mandatory, Celgene has developed its first submission using CDISC standards. This presentation will cover the following:

- Experience working with a vendor on SDTM retrospective mapping
- Developing ADaM metadata and SAS datasets
- Developing define files

Biography:

Ms. Wang has been doing statistical programming in pharmaceutical research for more than 17 years. She is currently directs the statistical programming group at Celgene Corporation, which works in the oncology, hematology, and inflammation and immunology therapeutic areas. Prior to Celgene, she worked at Johnson & Johnson for 13 years where she held positions of increasing responsibility leading to the direction of the data management and statistical programming team which supported the Internal



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Medicine and CNS Medical Affairs groups. While at Johnson & Johnson she successfully led numerous sNDA submissions. She has an M.S. degree in statistics from the State University of New York at Binghamton.

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Evaluation of Drug Induced Serious Hepatotoxicity (eDISH)

Ing-Ming Pan, Director, Programming, Janssen Pharmaceutical Companies of Johnson & Johnson

Abstract

This presentation will share the concept of Evaluation of Drug Induced Serious Hepatotoxicity (eDISH) and the tool which was created at the FDA for the detection of potential drug-induced liver injury.

The contents are referencing the published article “How a SAS/IntraNet tool was created at the FDA for the detection of potential drug-induced liver injury using data with CDISC standard” by Ted Guo, John Senior, Kate Gelperin, US FDA, Silver Spring, MD; and the Guidance for Industry -- Drug-Induced Liver Injury: Premarketing Clinical Evaluation, FDA, July 2009.

Biography:

Ing-Ming Pan, is the Director of Statistical Programming at Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD), with responsibilities for the statistical programming team working in the cardiovascular/metabolic disorder therapeutic area, as well as the established products area. She was Chair of the first SAPA Clinical Programming Workshop, in 2009.

Ing-Ming has been with Johnson & Johnson companies for more than 22 years. She joined Ortho Pharmaceutical Company in 1988 as a Programming Consultant and in 1989 moved to J&JPRD as a Scientific Programmer. Since then, she had increased responsibilities in data management, statistical programming, and project management in J&J Pharma Companies.

After receiving a BS degree and a MS degree from the National Taiwan University, Ing-Ming moved to the United States where she received a MS degree in Human Nutrition and Biochemistry from Mississippi State University. In addition, she is a certified Medical Technologist from American Society of Clinical Pathology (ASCP).

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Clinical Registries - What Biostatisticians and Programmers Need to Know



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Sherry Meeh, Senior Manager, Programming, Janssen Pharmaceutical Companies of Johnson & Johnson

Abstract

According to FDAAA, companies are now required to enter their trial basic results to ClinicalTrials.gov, an automation process is needed. Therefore, within Johnson and Johnson, we developed automation process to generate and post the required basic results statistics from a trial database directly to reduce the manual entries to improve its accuracy and efficiency. Our automation process begins with the clinical trial analysis SAS datasets that many companies use, and ends with a XML file validated according to the schema provided by ClinicalTrials.gov. SAS to XML automation are done through SAS macros. Biostatisticians and statistical programmers play key role in the automated process; their understanding of the new requirement has direct impact in the summary of the basic result. We piloted the automation process on over 50 clinical trials with various trial designs/database models from different therapeutic areas within Johnson & Johnson. The automation process can create a basic result summary file with accurate, consistent results, and quick turnaround time.

Biography:

Sherry Meeh has worked in statistical programming in health care industry since 1993, including pharmaceutical companies, Contract Research Organizations and a health insurance company. She has been a SAS user since 1992. Sherry has worked in a variety of therapeutic areas and different phases of clinical trial studies from earlier development phase, to phase I, II, III and Phase IV studies. She is currently working in the neuroscience therapeutic area at a research and development company of Johnson & Johnson. Sherry has a Master of Science degree in Statistics from Temple University.

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ClinicalTrials.gov Result Posting - Automation with Flexibility

Eric Sun, Senior Manager, Solution Leader, Sanofi

Abstract

Section 801 of the Food and Drug Administration Amendments Act (FDAAA) mandates the following information be loaded into ClinicalTrials.gov effective from 27SEP2009 for all trials for Drugs, Biologics and Devices:

- The basic results information described in the law.
- Information about serious and frequent adverse events (AE) observed.

To comply with the Law, the trial sponsor must register Phase I trials in patients and Phase II to IV trials as early as first regulatory approval and at the latest 21 days after first enrollment. To accommodate



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these additional requirements SOPs were established and cross functional teams were involved in the implementation collaboratively.

In this presentation, the following points are discussed.

- the very brief background and the drive of FDAAA Section 801
- the reaction and formation of a team at SANOFI for solution and implementation
- the experience learned in stages (e.g. the Result stat summary collection, loading, QC and official release)
- the critical points in developing automated application with the flexibility to adapt internal and external changes and needs.

Biography:

Eric Sun joined the pharma industry in 1990, worked for J&J, Novartis, Pfizer, and several other companies with positions Scientific programmer, programmer lead/manager in Immunobiology, CNS areas. He has worked for Sanofi for eight years as Senior Application Manager, leading world wide reporting automation projects.

Panel Discussion

Session Chair: Barry Schwab, Ph.D., Janssen Pharmaceutical Companies of Johnson & Johnson

Operating in a Global Environment for Biostatistics and Programming: Current Trends and Future Directions

Session Abstract

Pharmaceutical companies are continuing to evolve in their strategic placement of operations around the world. In turn, biostatistics and programming support within R&D is also evolving to include an expanded “footprint” in many regions. China and India, in particular, have taken center stage as locations of prime interest to augment capabilities. As such, the old paradigm of “outsourcing” has given way to the reality of managing a geographically diverse and global workforce.

This global workforce presents opportunities and challenges. What are the strategic advantages of establishing global operations relative to centralized operations? How will data standards, SOPs, quality and compliance be achieved? How will team-based structures impact the way we organize our



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biostatistical and programming operations? What are the skill sets staff will need for success in this environment?

In this session, an expert panel of Pharmaceutical and CRO executives will provide insight to these and other questions, and offer their perspectives on current trends and future directions when operating in a global workforce environment.

Biographies:

Barry Schwab, Ph.D.

Vice President, Clinical Biostatistics Head – Neuroscience and Established Products, Janssen Pharmaceutical Companies of Johnson & Johnson

Barry is Vice President and Head of Clinical Statistics for the Neuroscience, Pain and Established Products programs at the Janssen Pharmaceutical Companies of Johnson & Johnson. He also has responsibility for the statistical support provided to the clinical programs from the J&J office in Shanghai, China.

Barry has been with J&J for 27 years. He has provided statistical expertise and strategic direction to many of J&J's investigational compounds, with contributions to product approvals in psychiatry, neurology, pain, dermatology, anti-infectives and hematology/oncology. During his tenure with J&J, Barry spent 2 years working in the Zurich, Switzerland office of J&JPRI (1991-1992).

Barry is active in statistical professional society activities. He served on the PhRMA Biostatistics and Data Management Technical Group from 2000-2002. In 2003 he was Chair of the PhRMA/FDA Workshop on Risk Detection. He has been a Program Steering Committee member and Session Chair for the ASA/Biopharm-FDA Workshop, the DIA Statistical Workshop and the BASS Statistical conference. For the past 5 years, Barry has been the industry Co-Chair of the Annual FDA/DIA Statistics Forum, an open meeting to discuss regulatory and scientific issues associated with the development and review of therapeutic drugs and biologics. Barry is an Editorial Advisory Board Member for *Pharmaceutical Statistics, The Journal for Applied Statisticians in the Pharmaceutical Industry*.

Barry received his Ph.D. in Biostatistics from the Medical College of Virginia in 1984.

Raymond P. Bain, Ph.D.

Vice President, Biostatistics and Research Decision Sciences (BARDS), Global Clinical Development and Regulatory Affairs (GCDRA), Merck Research Laboratories (MRL)



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Since 2001, Dr. Bain has headed the Merck Research Laboratories (MRL) Global Biostatistics and Research Decision Sciences (BARDS) organization with responsibility for MRL Early and Late Development Statistics, Epidemiology, Health Economic Statistics and Scientific Programming groups. The Global MRL-BARDS organization develops and applies quantitative scientific methods in the targeting, discovery, development, manufacturing and marketing of pharmaceutical products through the design, conduct, analysis, interpretation and communication of pre-clinical, clinical, epidemiology and health economic investigations. Prior to joining Merck in 1999, Dr. Bain was a member of The Biostatistics Center at George Washington University (1986 – 1999) where he was Co-Director of the Center and Research Professor of Statistics. He received his PhD from the Department of Statistics and Biometry, Emory University School of Medicine in 1981. From 1981 to 1986 he was an Assistant Professor of Biometry, Medicine and Community Health at Emory University and a member of the Georgia Center for Cancer Statistics.

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Kimberly DeWoody, Ph.D.
Global Head, Biostatistics & Programming, Janssen Pharmaceutical Companies of Johnson & Johnson

Kim DeWoody is a Ph.D. statistician with over 25 years of pharmaceutical industry experience. She has held positions of increasing responsibility in pharmaceutical R&D with management responsibility of numerous functions including Clinical Biostatistics, Nonclinical Statistics, Statistical Programming, Health Economics and Medical Writing. Kim is currently the Global Head of Biostatistics & Programming for the Janssen Pharmaceutical Companies of Johnson & Johnson. She was a 2002 recipient of the Johnson Medal, the most prestigious award given for excellence in research and development within Johnson & Johnson, for innovation in design of the REMICADE ATTRACT study in rheumatoid arthritis.

Kim has a B.S. degree in Mathematics from University of Delaware, a M.S. degree in Statistics from Villanova University and a Ph.D. degree in Biostatistics from Temple University. She is a member of the American Statistical Association (ASA) and has held offices of President and Vice President for the Philadelphia Chapter of the ASA.

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Dominic Labriola, Ph.D.
Vice President, Global Biometric Sciences, Bristol-Myers Squibb Company



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Dominic Labriola, PhD is Vice President of Global Biometric Sciences at Bristol Myers-Squibb. He has had a 30 year career in the application of biostatistics to clinical research and has previously held positions at Memorial Sloan Kettering Cancer Center, Ives Laboratories and DuPont Pharmaceuticals. The Global Biometric Sciences (GBS) organization employees approximately 300 staff located in New Jersey, Connecticut, Belgium and India that support non-clinical and all human phases of drug development. In addition to leading GBS, Dominic also chairs the Clinical Sciences Committee and serves as a member of the Global Development and Medical Affairs Executive Leadership team for BMS. Dominic spends significant effort on the development of leadership skills in biostatisticians, to help prepare them for roles as members of drug development teams.

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C. S. Wayne Weng, Ph.D.
Senior Director, Biostatistics & Statistical Programming, Novo Nordisk Inc., Princeton, New Jersey

Wayne Weng has more than twenty years of pharmaceutical industry experience in statistical design/analysis, data management, outcomes research, and health-related quality of life research to support new drug development and post-approval product promotion in the therapeutic areas of diabetes, growth hormone, oncology, anti-infective, and allergy/asthma, etc. Management experience includes global projects, CROs and a department of 15 Statisticians and Programmers with 5 direct reports. Regulatory experiences include participation in meetings with the FDA for pre-NDA, NDA and Advisory Board meetings; participation in EMEA reviews and responses; and participation in preparation for NICE submissions in UK.

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Mei Wu
Head of global programming, Biostatistics and Programming, Sanofi

Mei Wu is the Global Head of Statistical Programming at Sanofi, where she directs statistical programming support across all therapeutic units and geographical locations in the department of biostatistics and programming. Mei received her M.S. in Statistics in 1995 from North Carolina State University. Mei started her career in the pharmaceutical industry as a statistical programmer at Merck Research Labs; she then assumed increasing responsibilities as a biostatistician for 11 years over her tenure at Merck before returning to the statistical programming arena to join Sanofi in 2007 as the Programming Therapeutic Area Deputy in the neurology and internal medicine areas.

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Irene Zhang

President/CEO, Everest Clinical Research Services Inc.

Irene has 25 years experience in statistics, data management, pharmaceutical new drug development, medical and clinical research, Contract Research Organization (CRO) business development and management. Her current role is as the President/CEO of Everest Clinical Research Services Inc.

Irene started Everest, a Contract Research Organization (CRO) in January 2004 following the Pfizer's acquisition of Pharmacia. Everest has grown substantially over the past seven years, providing clinical research services to pharmaceutical, biotechnology, and medical devices companies in the United States, Canada, Europe, Japan and China. Its services are focused on statistics, data management, medical writing, subject randomization and drug supply management, regulatory submission support, staff placement, and clinical trial management. Everest has full-service teams in two offices, located in Toronto, Ontario, Canada and in Little Falls, New Jersey, USA.

Prior to Everest Irene was the Director of Biostatistics and Data Management for the Global Medical Affairs organization of Pharmacia. Her career with Pharmacia started when she joined The Upjohn Company as the first Biostatistician of the International Biostatistics and Data Management center in 1992 when the operation was starting up. After a few short years she became the Manager of Clinical Data Management in 1996, and then the Director of the center in 1997 when it was Pharmacia & Upjohn.



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