



**Sino-American Pharmaceutical Professionals Association**

# Clinical Programming Workshop

October 10, 2009

Perspectives on Clinical Programming Work Challenges



# Sino-American Pharmaceutical Professionals Association

## Clinical Programming Workshop

### Agenda

#### *“Perspectives on Clinical Programming Work Challenges”*

Mingde Xia, Ph.D., SAPA President (2008-2009)

Jisong Cui, Ph.D., SAPA President (2009-2010)

Ing-Ming Pan, Workshop Chair

Workshop Executive Committee Members:

Danny Chaing, Varsha Chhatre, Cynthia He, Wenli Hu,  
Sarah Shiue, Ron Simpson, Mike Todd, Tricia Yeh, Aatiya Zaidi

[www.sapaweb.org](http://www.sapaweb.org)

**Saturday, October 10, 2009 (8:00 AM to 5:00 PM)**

**Jadewin Fine McDonnell Building**

**McDonnell Hall A01/02, Princeton University,**

**76 Washington Road, Princeton, New Jersey 08540**

#### **Registration and Breakfast**

**(8:00 AM to 9:00 AM)**

#### **Morning Session**

**(9:00 AM to 12:30 PM)**

**9:00 AM – 9:05 AM**

#### **Opening Remarks**

Mingde Xia, Ph.D., and Jisong Cui, Ph.D.

SAPA President (2008-2009), SAPA President (2009-2010)

**9:05 AM – 9:15 AM**

#### **Welcome and Meeting Agenda**

Ing-Ming Pan, Workshop Chair

Johnson & Johnson



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**9:15 AM - 12:30 PM**

**Morning Parallel Discussions**

Discussion 1	Discussion 2
CDISC / eSubmission Session Chair: Sarah Shiue / Varsha Chhatre	Drug Development Process Session Chair: Tricia Yeh
9:15 AM – 9:45 AM Taste of SDTM Changhong Shi, Beilei Xu, Merck	9:15 AM – 10:45 AM Clinical Trials: Basic Regulatory and Statistical Considerations Mary Johnson, Ph.D., PharmaNet
9:45 AM – 10:15 AM SDTMIG 3.1.2 vs SDTMIG 3.1.1, What Are the Major Differences Fugui Dong, Ph.D., PharmaNet	10:45 AM – 11:00 AM, Coffee Break
10:15 AM – 10:45 AM Insights into ADaM Matt Becker, PharmaNet	11:00 AM – 12:00 PM Fundamentals of Investigational New Drug Application Andrew Chang, Ph.D., PharmaNet
10:45 AM – 11:00 AM, Coffee Break	
11:00 AM – 11:30 AM Introduction to CDISC ADaM V2.1 and ADaMIG V1.0 John Troxell, Merck	12:00 PM – 12:30 PM Philadelphia University SAS Certificate Program Carol Matthews, United BioSource Co
11:30 AM – 12:00 PM CDISC Pilot II – SDTM/ADaM Implementation Issues Yuguang Zhao, and Sarah Shiue Eisai, and Merck	
12:00 PM – 12:30 PM Electronic Submission Process Denis Michel, Johnson & Johnson	

**Lunch**

**(12:30 PM to 1:30 PM)**



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#### Afternoon Session (1:30 PM to 5:00 PM)

#### 1:30 PM – 2:45 PM

#### Afternoon Parallel Discussions

Discussion 1	Discussion 2
Programming Technical / Process Tips Session Chair: Cynthia He	1: 30 PM – 2:15 PM Panel Discussion: Career Path for a SAS Programmer Session Chair: Aatiya Zaidi
1:30 PM – 2:00 PM Using Google to Solve SAS Problems Mike Todd, Nth Analytics	Panelists: Jaishri Alladi, Johnson & Johnson Denis Michel, Johnson & Johnson Peter Ouyang, Celgene Sarah Shiue, Merck
2:00 PM – 2:20 PM A Complete Derivation of Duration and Display in ISO 8601 Using SAS Program Joyce Gui, Helen Wang, and Sandy Wang Independent Consultant, Merck, and Rutgers	*****
2:20 PM – 2:40 PM Verifying Changes in Output Eric Carleen, PharmaNet	2:15 PM – 2:45 PM Market Your Talent Wenmei Ge, Johnson & Johnson

#### 2:45 PM – 3:00 PM

#### Coffee Break

#### 3:00 PM – 4:45 PM

#### Soft Skills

Session Chair: Danny Chaing	
3:00 PM – 3:45 PM	Business Communication Skills: A Powerful Factor for Your Career Judy West, English That Works, Inc
3:45 PM – 4:15 PM	Communication Skills: Techniques You Can Apply Lisa Lyons, Johnson & Johnson
4:15 PM – 4:45 PM	Panel Discussions Danny Chaing, Barry Schwab, Lisa Lyons, Judy West and Tricia Yeh Johnson & Johnson, English That Works, and PharmaNet

#### 4:45 PM – 4:50 PM

#### Conclusion of the Event Ing-Ming Pan

#### 5:00 PM – 8:00 PM, Dinner and Fellowship (optional)



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**Workshop Chair – Ing-Ming Pan:** Ms. Pan has been with Johnson & Johnson companies for over 20 years. She joined Ortho Pharmaceutical Company in 1988 as a Programming Consultant and in 1989 moved to Johnson & Johnson P.R.D. as a Scientific Programmer. Since then, she had increased responsibilities in data management, programming, and project management in Johnson & Johnson Pharma Companies. She is currently managing a team of SAS programmers in the Internal Medicine and Cardiovascular therapeutic areas at Johnson & Johnson. Prior to joining Johnson & Johnson she worked at the University of Texas Medical School in Houston and at the Hunterdon Medical Center in Flemington, NJ. After receiving a BS degree and an MS degree from National Taiwan University, Ms. Pan then moved to the US where she received an MS degree in Human Nutrition and Biochemistry from Mississippi State University. She is also a certified Medical Technologist (ASCP).

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### CDISC / eSubmission

**Session Chair: Sarah Shiue, Merck / Varsha Chhatre, Novartis**

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**CDISC Session Chair – Sarah Shiue:** Ms. Shiue is the Director of Scientific Programming responsible for the Merck scientific programming group in Rahway, New Jersey. She has been in the Pharmaceutical Industry for more than 20 years mostly at Johnson & Johnson and was at Aventis prior to joining Merck in 2005. She has broad experiences in reporting and global regulatory dossier submissions in several therapeutic areas and had involved closely in developing standard systems and processes at Johnson & Johnson and Aventis. Ms. Shiue was a member of the CDISC SDS and ADaM working groups in 2000-2007 representing Johnson & Johnson, Aventis or Merck respectively and had participated in the first two CDISC-FDA SDTM pilots.

**eSubmission Session Chair - Varsha Chhatre:** Ms. Chhatre has been working in the applications of Statistics and the Statistical Programming areas for more than 20 years. Currently as a Sr. Principal Programmer at Novartis Pharmaceuticals, she is supporting the Early Clinical Development (ED) studies in all therapeutic areas. She has been a SAS user for more than 10 years and e-Submission is one of her interests. Currently at Novartis, she is responsible for coordinating and reviewing ED deliverables, mostly CRTs required for all Novartis e-submissions. Ms. Chhatre has a Master degree in Applied Statistics from India, a Master degree in Statistics from University of Victoria, Canada and a Master's certificate in Project Management from George Washington University.

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#### Taste of SDTM

Changhong Shi and Beilei Xu, Merck

##### Abstract:

The Study Data Tabulation Model (SDTM) is a Clinical Data Interchange Standards Consortium (CDISC) standard. At Merck, pilot studies have been completed in which SDTM is implemented to the collected data up-front with the following proven advantages from SDTM:

1. standardization across studies.
2. facilitation of data integrity checking.
3. tabulation data structures readily leveraged for ADaM (Analysis Dataset Model) data setup.

This paper will describe these three advantages in detail.

##### Biography:

**Ms. Changhong Shi** is a Scientific Programming Analyst at Merck & Co., Inc. She has worked as a SAS programmer for 8.5 years. Before joining Merck, Ms. Shi had worked as an information specialist in Statistics Canada for one and half years. Her areas of expertise include the Base SAS, SAS Macro Language, SAS/CONNECT, Visual Basic, Java and Oracle.

**Ms. Beilei Xu** has about 12 years experience in SAS programming. Ms. Xu currently works in Merck Scientific Programming group.

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#### SDTMIG 3.1.2 vs SDTMIG 3.1.1, What Are the Major Differences

Fugui Dong, Ph.D., Manager, Database Programming, PharmaNet

##### Abstract:

CDISC has officially released the Study Data Tabulation Model, Version 1.2 (SDTM v1.2) and the SDTM Implementation Guide for Human Clinical Trials (SDTMIG v.3.1.2) at March 2009. Once the updated software is available, FDA will move to 3.1.2. This presentation will discuss some of the major changes introduced in 3.1.2 release.

##### Biography:

Dr. Dong is a Database Programming Manager at PharmaNet. He received his Ph.D. in Molecular Biology in 1997 and MS in System Analysis in 2000 from Miami University. Dr. Dong is an Oracle certified Oracle 8i and 9i professional and SAS Certified Advanced SAS 9 programmer. He has been involved in the SDTM conversion in the past 3 years.



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#### **Insights into ADaM**

**Matt Becker, PharmaNet**

##### **Abstracts:**

ADaM (Analysis Dataset Model) is meant to describe the data attributes such as structure, content, and metadata that are typically found in clinical trial analysis datasets. The ADaM models are built from the CDISC SDTM baseline. In this presentation, Mr. Becker will briefly cover the CDISC SDTM 3.1.1 model and then move into an in-depth review of ADaM. The goal is to provide the attendees knowledge of the ADaM model, how it relates to the CDISC SDTM base, and how it may help in reducing FDA review time.

##### **Biography:**

Mr. Matt Becker has twenty years of experience in contract drug development, specializing in statistical programming and related software development. He has been instrumental in the development and deployment of numerous statistical programming platforms. A recognized leader in statistical programming in SAS, Mr. Becker is a frequent speaker and leader at industry conferences such as PharmaSUG and SUGI.

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#### **Introduction to CDISC ADaM V2.1 and ADaMIG V1.0**

**John Troxell, Associate Director, Scientific Programming, Merck**

##### **Abstracts:**

The Analysis Data Model (ADaM) team of the Clinical Data Interchange Standards Consortium (CDISC) has drafted an ADaM Implementation Guide (IG). The IG describes requirements for the subject-level analysis dataset ADSL. The IG also describes and provides requirements for the new standard dataset structure for analysis datasets that contain multiple records per subject. This new standard structure supports most common statistical analyses, including, but not limited to, change from baseline, categorical, and time-to-event analyses. The presentation will provide an overview of ADaM and the IG, and an introduction to the new standard structure for analysis datasets.

##### **Biography:**

Mr. John Troxell wrote his first SAS program in 1977. He has degrees in English, Horticulture, and Statistics. Mr. Troxell currently holds position of Associate Director, Scientific Programming, at Merck, and has been the CDISC Analysis Data Model (ADaM) team lead since February 2008.



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#### **CDISC Pilot II - SDTM/ADaM Implementation Issues**

**Yuguang Zhao, Eisai**

**Sarah Shiue, Merck**

#### **Abstracts:**

The mission of the CDISC/FDA Integrated Data Pilot was to demonstrate that a data submission created using CDISC harmonized standards will meet the needs and expectations of FDA reviewers in conducting an integrated safety review of data from multiple studies and compounds. The pilot was to be utilized to evaluate data integration, workflow and process, semantic interoperability and standard analysis and reporting. This presentation will give an overview of a case study of experiences implementing the CDISC models and provide the industry with feedback on issues in implementing SDTM/ADaM.

#### **Biography:**

**Mr. Yuguang Zhao** originally came from Inner Mongolia of China. He graduated from University of Nevada-Reno with MS degree. He has been working in the pharmaceutical industry for over 10 years. He previously worked at Sanofi-Aventis. At present, Mr. Zhao is working at Eisai Medical Research as the director for global statistical analysis, essentially the statistical programming group. He used to be in the CDISC SDS team and participated in the CDISC first pilot as a pilot chair.

**Ms. Sarah Shiue** is the Director of Scientific Programming responsible for the Merck scientific programming group in Rahway, New Jersey. She has been in the Pharmaceutical Industry for more than 20 years mostly at Johnson & Johnson and was at Aventis prior to joining Merck in 2005. She has broad experiences in reporting and global regulatory dossier submissions in several therapeutic areas and had involved closely in developing standard systems and processes at Johnson & Johnson and Aventis. Ms. Shiue was a member of the CDISC SDS and ADaM working groups in 2000-2007 representing Johnson & Johnson, Aventis or Merck respectively and had participated in the first two CDISC-FDA SDTM pilots.



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#### **Electronic Submission Process**

**Denis Michel, Johnson & Johnson**

#### **Abstract:**

Global health authorities require clinical information in electronic format for the purpose of reviewing applications to market drugs and biologics. Electronic submissions have evolved over time, with increasing regulatory guidance and data standards. This presentation explores the process of electronic submission, regulatory review issues, and lessons learned for future submissions.

#### **Biography:**

Mr. Michel has worked in clinical data management and statistical programming at pharmaceutical companies and Contract Research Organizations since 1982. He has been a SAS user since 1985, and has presented papers at local and global user groups. He is currently managing a team of SAS programmers in the neuroscience therapeutic area at Johnson & Johnson. His focus areas include dictionary management and electronic submissions.

Mr. Michel has a BS in Biological Sciences from State University of New York at Stony Brook and MBA from Seton Hall University.



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#### Drug Development Process

**Session Chair: Tricia Yeh, Vice President, Biostatistics, PharmaNet**

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**Session Chair - Tricia Yeh:** Ms. Yeh has over 30 years experience in the pharmaceutical and CRO industry. She provides statistical input in the development of protocols and CRFs and manages biostatistical activities in the preparation of clinical trial reports and NDA/PLA submissions. She has worked in a wide variety of therapeutic areas, notably cardiovascular, oncology, neurology, and endocrine/metabolic indications, and has extensive experience with integration of legacy databases and performing interim analyses for data monitoring boards. She has a MS degree in Biostatistics from University of Cincinnati and a MS degree in Botany from Miami University.

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#### Clinical Trials: Basic Regulatory and statistical Considerations

**Mary Johnson, Ph.D., Executive Vice President, Biostatistics, PharmaNet**

**Abstract:**

Part I - An overview of how experimental medical products (drug, biologics, devices) are developed and tested to determine if they are safe and effective for use in humans.

Part II – An overview of statistical principles in clinical trials (including bias, blinding, randomization, and trial design issues).

**Biography:**

Dr. Johnson has served as a statistical consultant to pharmaceutical clients for over 20 years, assisting in design of drug development programs and advising clients on statistical and regulatory aspects of NDA/PLA submissions for a wide variety of therapeutic indications. Dr. Johnson also spent 8 years as a statistical reviewer and group leader in the Division of Biometrics at the FDA. She is familiar with regulatory guidelines and processes, and has helped numerous clients develop efficient and statistically sound research programs to gain rapid marketing approval. She received her PhD in Biostatistics at Yale University.

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#### **Fundamentals of Investigational New Drug Application**

**Andrew C. Chang, Ph.D., Executive Director, PharmaNet Consulting**

#### **Abstract:**

The following topics will be presented:

- General introduction of the FDA
- What is an IND
- Clinical trial regulations
- IND review process (focus on the process used in CBER).

#### **Biography:**

Dr. Chang has more than 19 years of experience in the development of biologics and pharmaceuticals. At his current capacity as an Executive Director, PharmaNet Consulting, Dr. Chang has advised clients on top-level strategic planning and evaluations related to biological-product development in the US, Europe, and Asia to efficiently bring products from R&D to marketing approval. He has consulted on regulatory submissions from pre-IND to marketing applications; regulatory pathways including assessing the possible regulatory jurisdiction, orphan drug designation, and fast track and accelerated approval; FDA and EMEA requirements on chemistry, manufacturing and control (CMC); immunogenicity risk assessment for therapeutic protein products; viral safety for naturally derived (including blood products) or recombinant protein products; comparability studies in supporting manufacturing changes during either product development or post-marketing; and strategic planning for developing biosimilars. He has created and delivered training programs to clients on quality related issues (e.g., specification, stability, quality by design, process validation, potency standard and assays, and impurities), and on current Good Manufacturing Practices (cGMP). Dr. Chang provided mock pre-approval inspections to assess whether clients were in compliance with cGMP and their readiness for the FDA inspection. His consulting services assisted clients on their product approvals after first cycle review by regulatory authorities.

Prior to joining PharmaNet in 2006, Dr. Chang served more than 11 years at US FDA, most recently as an Associate Director for Policy and Regulation and Senior Regulatory Scientist in the Division of Hematology, Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER). He is known nationally and internationally for his significant scientific and regulatory contributions to the development, approval and post market surveillance of recombinant and naturally-derived products. During his tenure at the FDA, Dr. Chang had served as the primary product reviewer on over 40 original IND submissions and hundreds of amendments. He had served as the review committee chairperson for the



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licensures of four new and novel recombinant and naturally-derived products, and for the approval of hundreds of post-marketing supplements. In 2002, FDA recognized Dr. Chang as the FDA regulatory expert in the regulation of new and novel recombinant products as well as naturally-derived biological products. He clearly is considered one of the foremost regulatory experts in recombinant and naturally-derived protein products.

While at FDA, Dr. Chang was known as a leading FDA and CBER spokesperson and has presented the FDA perspective at many national and international meetings. In addition, he has served on numerous committees, such as FDA Committee for Follow-On Protein Pharmaceuticals, CBER's Chemistry, Manufacturing and Control (CMC) Coordinating Committee (CMCCC), CBER representative at CDER Manufacturing Science Working Group, CMC Review Template Working Group, FDA Comparability Working Group, and CBER Working Group for Manufacturing Changes. Dr. Chang also served as the FDA deputy topic leader for ICH Q5E guideline, and the FDA observer for European and US Pharmacopeia's Expert Groups on Blood and Blood Derived Products. Furthermore, he worked closely with CBER's Office of Compliance and Biologics Quality on FDA inspection program including Team Bio and CBER pre-license/approval inspections.

His formal scientific training includes a Doctor of Philosophy degree in Biochemistry from the State University of New York, 1991, and a Bachelor of Sciences degree in Pharmaceutical Chemistry from the China Pharmaceutical University, 1982. Supplementing his academic degrees, Dr. Chang also studied at the National Institute of Allergic and Infectious Diseases, National Institutes of Health as a postdoctoral fellow from 1991 until he joined CBER in 1995. Consulting Expertise: Regulatory considerations for natural, recombinant, and combination products, product comparability, follow-on/biosimilar protein products, viral safety, immunogenicity, cGMP audit, and interpretation of FDA regulations, policies, and guidances.

Andrew C. Chang, Ph.D.

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#### **Philadelphia University SAS Certificate Program**

**Carol Matthews, Sr. Director, Clinical Programming, United BioSource Corporation**

#### **Abstract:**

There are several key components to being a successful statistical programmer in the pharmaceutical industry that go beyond just understanding how SAS works. While SAS offers great courses that teach how to use the language, Philadelphia University has the only program in the area that carefully screens applicants and provides in-depth training specifically targeted to the pharmaceutical industry.

#### **Biography:**

Ms. Carol Matthews is currently a Senior Director of Clinical Programming for United BioSource Corporation, Biotechnology Solutions. She has been an adjunct faculty member in Philadelphia University's SAS Programming certification program since 1998, has presented audio conferences through FDA News, and has presented several seminars on effective clinical programming practices at the annual Pharmaceutical Industry SAS User's Group conference. Ms. Matthews recently co-authored the book Validating Clinical Trial Data Reporting With SAS® with Brian Shilling.



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#### Programming Technical/Process Tips

Session Chair: Cynthia He, Schering Plough

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**Session Chair – Cynthia He:** Ms. He is a manager in Global Scientific Programming Department at Schering-Plough Research Institute. She has over 20 years of SAS programming experience and 8 years of management experience in CRO and Pharmaceutical companies including Covance, PharmaNet, Merck, and Schering-Plough. She has a master's degree in Statistics from Rutgers University.

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#### Using Google to Solve SAS Problems

Mike Todd, Nth Analytics

**Abstract:**

SAS has a long history as the language for statistical programming in the pharmaceutical industry. In the past 30+ years, most, if not all, of the problems statistical programmers face on a day-to-day basis have been solved by somebody. Usually there is a paper somewhere on the Internet about it. Using Google queries, statistical programmers can leverage the vast SAS knowledge base on the Internet, and get quick answers to a variety of problems, such as:

- Different algorithms for subject age calculations
- Finding row differences (i.e. simulating the lag function) in PROC SQL.
- Methods for printing “Page 1 of n” in RTF outputs
- How to use hexadecimal codes in SAS statements
- Reading a Chinese-encoded SAS dataset

**Biography:**

Mr. Mike Todd is the President of Nth Analytics, a Clinical Biometrics Services firm. He has over 25 years of pharmaceutical experience with an extensive background in statistical analysis, and is a recognized expert on CDISC SDTM. Mr. Todd has a B.A. in English Literature from Penn State, a M.A. in Experimental Psychology from the University of South Carolina, and a M.S. in Statistics from Rutgers University.



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#### **A Complete Derivation of Duration and Display in ISO 8601 Using SAS Program**

Joyce Gui, Independent Consultant

Helen Wang, Department of Scientific Programming, Merck

Sandy Wang, Rutgers, the State University of New Jersey

#### **Abstract:**

In clinical trials, an adverse event (AE) can occur anytime during the course of the study. In data analysis, it is common to relate AE information with study medication which is referred to as *time since last dose*. If the duration variable is included for regulatory submission, it must follow the ISO 8601 duration formats as described in the CDISC SDTM Implementation Guide (Version 3.1.1) section 4.1.4.3. This paper will use adverse experience start date/time and the study medication start date/time to derive the time since last dose based on defined rules using SAS programs, and display the duration in ISO 8601 duration format.

#### **Biography:**

**Ms. Joyce Gui** holds M.S. degrees in System Engineering and Statistics. She worked in the financial industry as a SAS programmer for a few years before joining Merck. At Merck, Joyce worked for 5 years in the data management department, and 3 years in the Biostatistics and Research Decision Sciences department providing SAS programming for data analysis and reporting to biostatisticians for clinical trials and NDA submissions. She left Merck in July 2009, and now works as an independent consultant to provide table, listing and patient profiles for the need of clinical trial development and regulatory submission for pharmaceutical companies.

**Ms. Helen Wang** holds a M.S. degree in Statistics. She has extensive experiences in SAS programming and statistical analysis. Ms. Wang has been using SAS for statistical analysis and reporting for 15 years in different industries including pharmaceutical, financial, telecom, and banking.

**Ms. Sandy Wang** works as a Statistical Programmer (contract) in Biostatistics and Research Decision Sciences Dept. at Merck since Jan. 2009. She's also a part-time M.S. student in Statistics & Biostatistics at Rutgers, the State University of New Jersey. Ms. Wang holds a M.S. degree in Mechanical Engineering from the University of Toledo.



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#### **Verifying Changes in Output**

Eric Carleen, Associate Director, PharmaNet

#### **Abstract:**

Often during a study a minor change is made to a program, and it is expected that the result will change only a small number of tables and listings in a small way. This talk will present methods to verify that expectation programmatically by automating a 100% comparison of the “before” and “after” output. This method works on LST and RTF files produced by SAS. Hundreds of tables can be validated in few minutes.

#### **Biography:**

Mr. Eric Carleen is an Associate Director at PharmaNet, where he has been programming since 2003. He also spent ten years at Carter-Wallace as a statistician, programmer, and associate director of UNIX and Windows systems and networking; one year as a programmer at Sterling Drug; and nine years at the University of Rochester doing NIH research and pharmaceutical work as a statistician, SAS programmer, and database programmer. Mr. Carleen has a Master’s degree in Statistics from the University of Rochester.



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#### Panel Discussion: Career Path for a SAS Programmer

**Session Chair: Aatiya Zaidi, Novo Nordisk**

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**Session Chair – Aatiya Zaidi:** Ms. Zaidi is the Senior Manager of Statistical Programming at Novo Nordisk Inc. She has 17 years of SAS programming experience and 10 years of management experience in CRO and pharmaceutical companies that include Covance, Wyeth-Ayerst Research, and Novo Nordisk Inc."

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#### Biography of Panelists:

##### **Jaishri Alladi, Johnson & Johnson**

Ms. Alladi has 20 years of Statistical Programming experience spanning a variety of therapeutic areas in the CRO/Pharmaceutical industry. She has held functional area management responsibilities for the last 13 years.

In the last nine years at Johnson & Johnson, Ms. Alladi has provided programming leadership across several regulatory submissions in the area of Rheumatology. She is currently responsible for overseeing programming operations for the Virology therapeutic area and early development studies (both small and large molecules) in the therapeutic areas of Immunology and Oncology.

##### **Denis Michel, Johnson & Johnson**

Mr. Michel has worked in clinical data management and statistical programming at pharmaceutical companies and Contract Research Organizations since 1982. He has been a SAS user since 1985, and has presented papers at local and global user groups. He is currently managing a team of SAS programmers in the neuroscience therapeutic area at Johnson & Johnson. His focus areas include dictionary management and electronic submissions.

Mr. Michel has a BS in Biological Sciences from State University of New York at Stony Brook and MBA from Seton Hall University.



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#### Biography of Panelists (cont.):

**Peter Ouyang, Ph. D., Vice President, Biostatistics and SAS Programming, Celgene Corporation**

Dr. Ouyang received his Ph.D. in Statistics from SUNY at Stony Brook in 1982, and is a member of ASA, ENAR, ICSA, and DIA. He has extensive experience in statistical design, analysis, and reporting in the pre-clinical area and all phases of clinical drug development in many therapeutic areas. His leadership has resulted in several successful drug applications in allergy, anti-infective, CNS, diabetes, pain and oncology. He has organized many short courses and professional meetings. His research interests include adaptive clinical trial design, group sequential methods, multiple comparisons, analysis of longitudinal data, computer assisted trial design, and PK/PD modeling. He also co-authored the SOP to govern the conduct of interim analysis via a Data Monitoring Committee in Johnson & Johnson P.R.D..

**Sarah Shiue, Director of Scientific Programming, Merck**

Ms. Shiue is the Director of Scientific Programming responsible for the Merck scientific programming group in Rahway, New Jersey. She has been in the Pharmaceutical Industry for more than 20 years mostly at Johnson & Johnson and was at Aventis prior to joining Merck in 2005. She has broad experiences in reporting and global regulatory dossier submissions in several therapeutic areas and had involved closely in developing standard systems and processes at Johnson & Johnson and Aventis. Ms. Shiue was a member of the CDISC SDS and ADaM working groups in 2000-2007 representing Johnson & Johnson, Aventis or Merck respectively and had participated in the first two CDISC-FDA SDTM pilots.



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#### **Market Your Talent**

**Wenmei Ge, Johnson & Johnson**

**Abstract:**

Are you interested in learning more about Networking 101, how to write a great resume or how to prepare for a phone & face-to-face Interview? In good times or bad, especially in a time when change comes so fast, we need to be ready when opportunities knock on the door. In this presentation, Ms. Wenmei Ge will be sharing some tips on how to market your talent in this fast-changing world.

**Biography:**

Ms. Wenmei Ge is currently a Programming Manager in the Process Support group at Johnson & Johnson Pharmaceutical Research & Development. In her role, she is responsible for the internal DMC and IA supports. Wenmei began her career with the Johnson & Johnson organization in 2005. Prior to joining Johnson & Johnson P.R.D., she served as a lead senior statistical programmer at Advanced Biologics LLC. Wenmei holds a Masters degree in Computer Science from St. Joseph's University and a Bachelor of Science in Engineering from Shanghai University. Ms. Ge chairs the Titusville A.S.I.A (the Asian Society for Innovation & Achievement) and was named recipient of the 2006 and 2008 Johnson & Johnson A.S.I.A Impact Awards.



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#### Soft Skills

**Session Chair: Danny Chaing, Johnson & Johnson**

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**Session Chair - Danny Chaing:** Mr. Chaing started his pharmaceutical career in Statistics at Hoechst-Roussel Pharmaceutical, Inc in 1977. In the 12 years at American Home Products Corporation (1979-1991), he led data management, statistics, and programming work in multiple approved NDAs, and Rx-to-OTC conversions. Mr. Chaing concentrated on Computer-Assisted NDA (CANDA) technologies while working for Rhone-Poulenc Rorer (RPR) from 1991 to 1995. He joined Janssen Research Foundation of Johnson & Johnson in 1995 and had increased responsibilities in data management, and programming in Johnson & Johnson Pharma Companies. His current position is Head, Statistical Programming – CNS/Internal Medicine/Virology, Biostatistics & Programming Center of Excellence (CoE), Global Drug Development (GDO) of Johnson & Johnson. Danny has been active in SAPA, ICSA, and PhRMA (BDMTG).

Mr. Chaing earned his Bachelor of Science in Statistics from Fu-Jan University, Taiwan. He has a Master degree in Statistics and a Master degree in Computer Science from Rutgers University.

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#### **Business Communication Skills: A Powerful Factor for your Career**

**Judy West, English That Works, Inc**

##### **Abstract:**

Today's corporations employ many multinationals whose technical and scientific expertise is crucial in today's global marketplace. A major job requirement is the ability to communicate clearly and confidently and to present one's ideas appropriately and effectively. When this is accomplished, employees can significantly leverage their knowledge and skills as credible and contributing members of the team and organization.

- What are the business communication and cultural awareness skills necessary for success in today's business environment?
- How can you improve your professional visibility and credibility at work?

Find out why many executives say that communication skills are the number one factor that determined their rise to the top. Learn why what you know, who you know, and who knows you can make a major difference in your career.

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#### **Biography:**

Judy West, founder and president of English That Works, Inc. has thirty years of successful experience developing, and teaching courses, training programs, workshops, and private coaching sessions that improve the oral and written performance of professionals who speak English as their second language. She has provided services at Bristol Myers Squibb, Johnson and Johnson, Ethicon, Janssen, and Wyeth as well as other research, technical, manufacturing, and service corporations, government offices, colleges, and community-based organizations. Training provided by Ms. West focuses on immediately useful language and cultural awareness skills needed for communicative and interpersonal success in business and social settings. Course offerings include American English Pronunciation, Speaking Solutions, Assertive Communication, Writing for Multinationals, and customized individual coaching.

Participants consistently report the following positive results:

- Greater ability to communicate effectively and persuasively
- More productive relationships and greater participation on teams and in meetings
- Enhanced professional image
- Expanded active English vocabulary
- Decreased misunderstandings due to oral language/accent
- Increased understanding of American idioms and culture
- Heightened self confidence

Ms. West is a Magna Cum Laude graduate of the University of Pennsylvania where she earned a Bachelor of Arts in Sociology and a Master of Science in Education.



# Sino-American Pharmaceutical Professionals Association

## Clinical Programming Workshop

### Abstract and Biography

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#### **Communication Skills: Techniques You Can Apply**

Lisa Lyons, Johnson & Johnson

#### **Abstract:**

Effective communication requires bringing together different points of view and relaying that information without losing clarity. Regardless if it is a face-to-face conversation or an e-mail exchange, a meaningful message entails establishing a connection that leaves a powerful impression. This presentation will build upon the key concepts presented in “Business Communication Skills: A Powerful Factor for Your Career” and provide the audience with techniques they can apply in everyday situations.

#### **Biography:**

Ms. Lisa Lyons has over ten years experience in statistical programming for the pharmaceutical industry. Currently she is a Manager at Johnson & Johnson where she is responsible for management of Established Products statistical programming team. She has excellent communication skills and her responsibilities include coaching, developing and mentoring staff for professional growth.

Ms. Lyons is a graduate of Drexel University in Philadelphia, PA where she earned a MS in Clinical Research. Ms. Lyons also holds a SAS Certification from Philadelphia University in Philadelphia, PA and a BS in Psychology from College of New Jersey, Trenton, NJ.



# Sino-American Pharmaceutical Professionals Association

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#### Panel Discussions: Soft Skills

#### Biography of Panelists:

##### **Barry Schwab, Ph.D., Johnson & Johnson**

Dr. Schwab is Vice President and Head of Clinical Statistics for the Neuroscience, Pain, Anti-infectives/Metabolism and CV/Urology programs at Johnson & Johnson.

Dr. Schwab has been with Johnson & Johnson for 25 years. He has provided statistical expertise and strategic direction to many of Johnson & Johnson's investigational compounds, with contributions to product approvals in psychiatry, neurology, pain, dermatology, anti-infectives and hematology/oncology. During his tenure with Johnson & Johnson, Dr. Schwab spent 2 years working in the Zurich, Switzerland office of Johnson & Johnson PRI (1991-1992).

Dr. Schwab 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 since 2004. For the past 3 years, Dr. Schwab 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. Dr. Schwab is an Editorial Advisory Board Member for *Pharmaceutical Statistics, The Journal for Applied Statisticians in the Pharmaceutical Industry*.

Dr. Schwab received his Ph.D. in Biostatistics from the Medical College of Virginia.

##### **Tricia Yeh, Vice President, Biostatistics, PharmaNet**

Ms. Tricia Yeh has over 30 years experience in the pharmaceutical and CRO industry. She provides statistical input in the development of protocols and CRFs and manages biostatistical activities in the preparation of clinical trial reports and NDA/PLA submissions. She has worked in a wide variety of therapeutic areas, notably cardiovascular, oncology, neurology, and endocrine/metabolic indications, and has extensive experience with integration of legacy databases and performing interim analyses for data monitoring boards. She has a MS degree in Biostatistics from University of Cincinnati and a MS degree in Botany from Miami University.



# Sino-American Pharmaceutical Professionals Association Clinical Programming Workshop

## Directions

Direction to the workshop:

The workshop will be held in McDonnell Building, Princeton University, Princeton, New Jersey. See below the map for the building and the parking lot information. There will be "SAPA" signs available to direct you to the parking lot and McDonnell building.

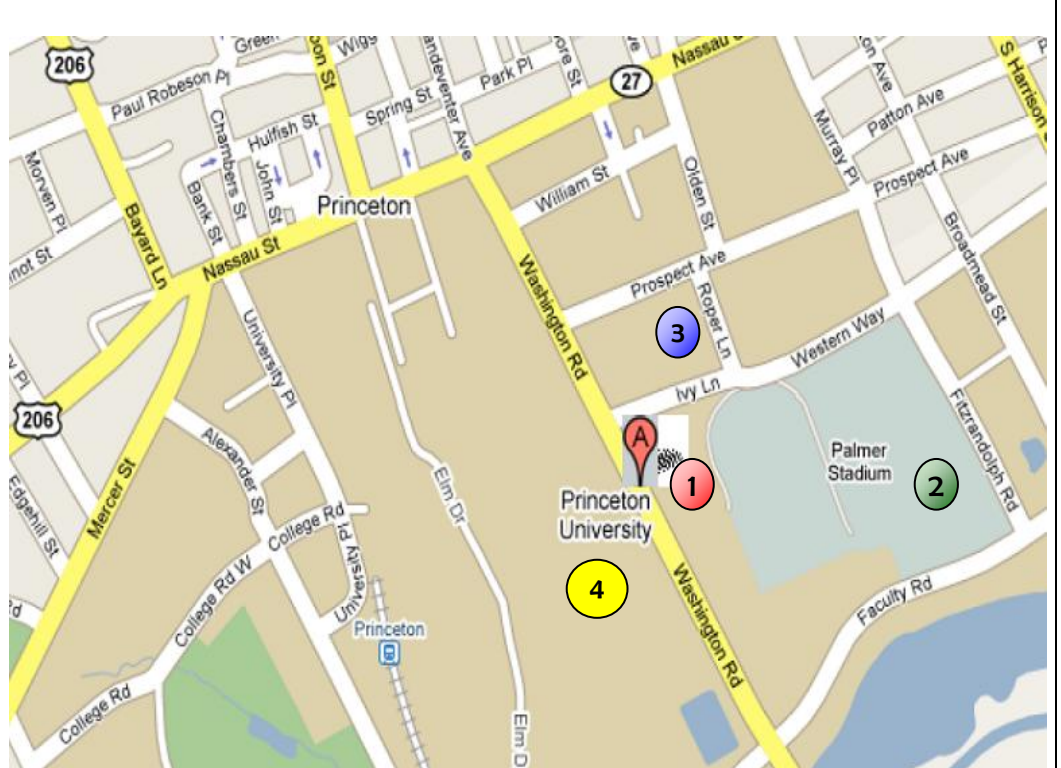
McDonnell Building and parking:

1 Jadewin Fine McDonnell Building (76 Washington Rd Princeton, NJ 08540)

2 Parking Lot 21 (Fitzrandolph Rd)

3 Additional parking (Ivy Ln)

4 Parking under construction





# Sino-American Pharmaceutical Professionals Association

## Clinical Programming Workshop

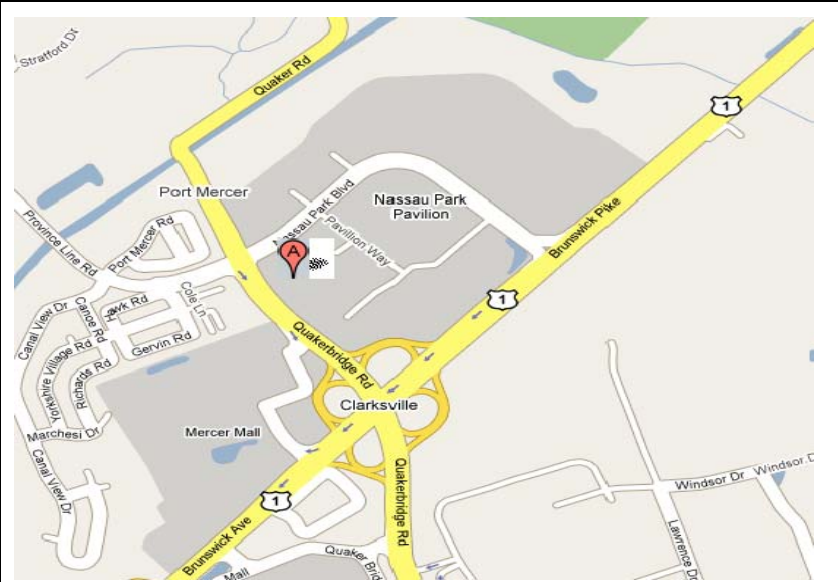
### Directions

**Direction to dinner at Supper Star East Buffet:**

The optional dinner will be in Super Star East Buffet, located right off the Route 1, about 4.6 mile / 7 minutes from the McDonnell Building. The address and the driving direction is provided below

**Super Star East Buffet**  
 Phone: 609.987.9168  
 311 Nassau Park Blvd.  
 Princeton/West Windsor  
 (In The Same Shopping Center as Wal-Mart and The Home Depot, Next To Sam's Club)

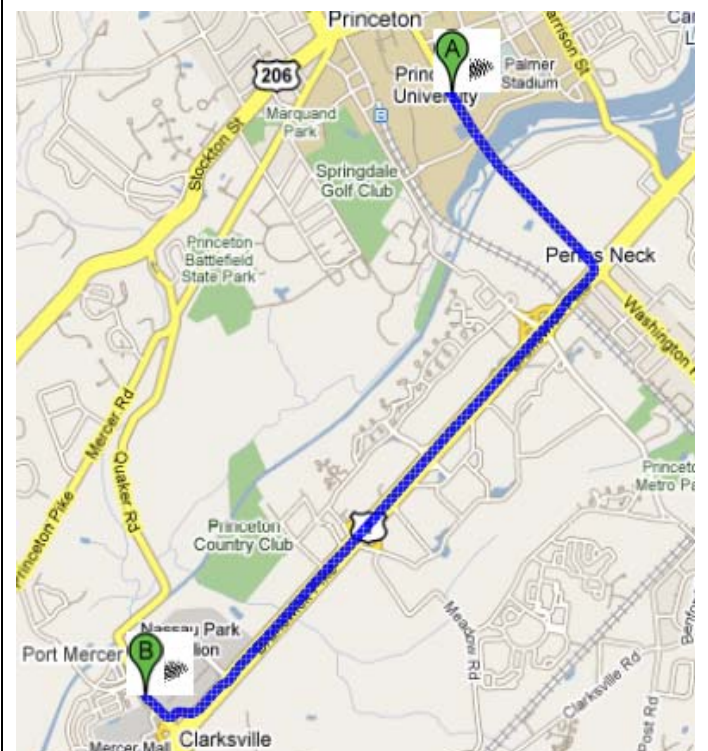
Dinner Buffet	Price
Adult	\$16
(3-6)	\$7
(7-11)	\$8



**The driving directions from Princeton University to Super Star East Buffet:**  
 Total: 4.6 mi - about 7 mins

1. Head southeast on Washington Rd toward Faculty Rd	1.2 mi
2. Turn right at Brunswick Pike/US-1	2.8 mi
3. Slight right toward Quakerbridge Rd	0.2 mi
4. Take the ramp onto Quakerbridge Rd	0.4 mi
5. Turn right at Nassau Park Blvd	331 ft

Destination will be on the right





# Sino-American Pharmaceutical Professionals Association

## Clinical Programming Workshop

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## *Thanks*

### Volunteers

Cha-Chi Lo	Johnson & Johnson
Eugenia Waslin	Johnson & Johnson
Sherry Meeh	Johnson & Johnson
Zhenhong Bao	RUBiotech
Jayeeta Ghosh	RUBiotech
Jimin Zhang	RUBiotech
Rui Ding	RUBiotech
Ying Zhang	RUBiotech
Shaoyou Wang	NJIT CSSA
Han, Jia	NJIT CSSA
He, Jieru	NJIT CSSA
Miao, Wei	NJIT CSSA
Sheng, Silu	NJIT CSSA
Wu, Zheqiong	NJIT CSSA

### SAPA

Bao-Guo Huang	Sanofi – Aventis
Cai Li	Merck
Helena Feng	SAPA
Jian Zhu	Novartis
Jiangfan Li	Johnson & Johnson
Jianji Wang	BMS
Jisong Cui	Merck
Jiwen Chen	BMS
Kevin Chen	Schering-Plough
Lian Huang	Johnson & Johnson
Mingde Xia	Johnson & Johnson
Xiaohui Mei	Boehringer-Ingelheim
Xiaoying Zhang	Alpharma
Xing Li	ISPOR
Yan Xia	Shering-Plough