



Sino-American Pharmaceutical Professionals Association

Clinical Programming Workshop

“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, Mike Todd, Tricia Yeh, Aatiya Zaidi

www.sapaweb.org

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

McDonnell Hall A01/02, Princeton University, Princeton, New Jersey 08544

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
1. 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
2. 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
3. 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	12:00 PM – 12:30 PM Philadelphia University SAS Certificate Program Carol Matthews, United BioSource Co
4. Introduction to CDISC ADaM V2.1 and ADaMIG V1.0 John Troxell, Merck	
5. CDISC Pilot II – SDTM/ADaM Implementation Issues Yuguang Zhao, and Sarah Shiue Eisai, and Merck	
6. 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 – 2:40 PM

Afternoon Parallel Discussions:

Discussion 1	Discussion 2
Programming Technical / Process Tips Session Chair: Cynthia He	Round Table Discussions Session Chair: Aatiya Zaidi
1:30 PM – 2:00 PM Using Google to Solve SAS Problems Mike Todd, Nth Analytics	
2:00 PM – 2:20 PM A Complete Derivation of Duration and Display in ISO 8601 Using SAS Program Helen Wang and Joyce Gui, Merck	
2:20 PM – 2:40 PM Verifying Changes in Output Eric Carleen, PharmaNet	

2:45 PM – 4:45 PM

Soft Skills:

Session Chair: Danny Chaing	
2:45 PM – 3:30 PM	Business Communication Skills: A Powerful Factor for Your Career Judy West, English That Works, Inc
3:30 PM – 3:45 PM	Coffee Break
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, Ing-Ming Pan, 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)