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
# Clinical Programming Workshop

## 9:15 AM - 12:30 PM  
**Morning Parallel Discussions**

### Discussion 1  
CDISC / eSubmission  
Session Chair: Sarah Shiue / Varsha Chhatre

1. Taste of SDTM  
   Changhong Shi, Beilei Xu, Merck

2. SDTMIG 3.1.2 vs SDTMIG 3.1.1, What Are the Major Differences  
   Fugui Dong, Ph.D., PharmaNet

3. Insights into ADaM  
   Matt Becker, PharmaNet

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

### Discussion 2  
Drug Development Process  
Session Chair: Tricia Yeh

9:15 AM – 10:45 AM  
Clinical Trials: Basic Regulatory and Statistical Considerations  
Mary Johnson, Ph.D., PharmaNet

10:45 AM – 11:00 AM, Coffee Break

11:00 AM – 12:00 PM  
Fundamentals of Investigational New Drug Application  
Andrew Chang, Ph.D., PharmaNet

12:00 PM – 12:30 PM  
Philadelphia University SAS Certificate Program  
Carol Matthews, United BioSource Co

---

**Lunch**  
*(12:30 PM to 1:30 PM)*
Afternoon Session
(1:30 PM to 5:00 PM)

1:30 PM – 2:40 PM  Afternoon Parallel Discussions:

<table>
<thead>
<tr>
<th>Discussion 1</th>
<th>Discussion 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Programming Technical / Process Tips</td>
<td>Round Table Discussions</td>
</tr>
<tr>
<td>Session Chair: Cynthia He</td>
<td>Session Chair: Aatiya Zaidi</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Session Chair: Danny Chaing</th>
</tr>
</thead>
</table>

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)