# Sunday (June 26th, 2011)

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Instructor(s)</th>
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</thead>
<tbody>
<tr>
<td>8:00 AM - 5:00 PM</td>
<td><strong>short courses</strong></td>
<td>H.M. James Hung and Sue-Jane Wang, FDA</td>
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<tr>
<td></td>
<td>1. Multiple Comparisons in Clinical Trials</td>
<td>Mei-Chiung Shih &amp; Balasubramanian Narasimhan, Stanford Univ.</td>
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<td></td>
<td>2. Design and Analysis of Group Sequential Trials: Recent Advances and Software</td>
<td>Frank Bretz, Novartis, and Jose Pinheiro Johnson &amp; Johnson</td>
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<td></td>
<td>3. Dose finding studies: methods and implementation</td>
<td>Gordon Lan, Johnson &amp; Johnson</td>
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<td>4. Group sequential method in survival analysis</td>
<td>Tie-Hua Ng, FDA</td>
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<td>1:00 AM - 5:00 PM</td>
<td>5. Concepts in equivalence/noninferiority testing: issues and challenges</td>
<td>Dhammika Amaratunga, Johnson &amp; Johnson</td>
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<td></td>
<td>7. Strategies for extracting reliable information from Megavariate data</td>
<td>Anthony An, SAS</td>
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<td>8. Using Replication Methods to Analyze Survey Data in SAS Software</td>
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## Social program: Mixer

7:00 PM - 9:00 PM

# Monday (June 27th, 2011)

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Organizer(s)</th>
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| 8:30 AM -10:30 AM | **Keynote lectures**  
  David Donoho, Stanford Univ.  
  Ji Zhang, Sanofi-aventis U.S. LLC. | Gang Zheng & Colin Wu, NHLBI                                                |
|              | **Break**                                                            | Tian Zheng (Columbia Univ)                                                   |
| 10:30 AM-10:45 AM | **Parallel Sessions**                                                 | Devan Mehrotra & Weili He, Merck & Co., Inc.                                 |
| 10:45AM-12:25 PM | 2 Statistical challenges arising from design and analysis of NIH studies | Zhengjun Zhang, Univ. of Wisconsin                                           |
|              | 3 Bayesian modeling and computation                                   | Qi Jiang, Amgen & Mat Soukup, FDA                                            |
|              | 5 Enhancing Probability of Success Using Modeling & Simulation       | Yufeng Liu & Dacheng Liu, UNC Chapel Hill                                   |
|              | 11 Financial Statistics, Risk Management, and Rare Event Modeling    | Hulin Wu, Univ. of Rochester                                                 |
|              | 13 Innovative Drug Safety Graphics Presentation                       | Mei-Ling Ting Lee, Univ. of Maryland                                         |
|              | 22 Topics in Statistical Machine Learning and High Dimensional Data Analysis | Yang Feng & Tian Zheng, Columbia Univ.                                       |
|              | 36 Differential Equation Models for Gene and Protein Networks         | Xiaoxi Zhang & Chunming (Mark) Li, Pfizer Inc.                               |
|              | 66 Lifetime data analysis                                            | Cunshan Wang, Pfizer Inc; Sara Hughes, ViiV HealthCare; Dan Meyer, Pfizer Inc; and Christy Chuang-Stein, Pfizer Inc. |
|              | 68 high dimensional statistical learning                              |                                                                                |
|              | 72 Predictive Modeling of Clinical Trial Enrollment and Drug Supply   |                                                                                |
|              | 73 Statistical Issues in Late-Stage HIV Clinical Trials               |                                                                                |

12:25 PM - 2:00 PM **Lunch Break**
Parallel Sessions

20 Statistical methods in biomarker discovery
Liansheng Tang, George Mason Univ.

44 Cox Model with Time-Varying Covariates
Zhongxin (John) Zhang & Surya Mohanty, Johnson & Johnson

47 High-dimensional classification and clustering methods with applications
Inchi Hu, Hong Kong Univ. of Sci. and Tech.

51 Mixture Models
Yuejiao Cindy Fu, York Univ. & Yongzhao Shao, NYU

52 Design and Analysis of Biomedical Studies
Qiong Yang, Boston Univ. & Yongzhao Shao, NYU

60 Novel approaches to the genetic dissection of complex traits
Bin Nan, Univ. of Michigan

82 Non-/Semi-Parametric Models for Complex Data
Judy Huixia Wang, NCSU

84 Time to event data analysis
Cheng-Shiu Leu, Columbia Univ.

87 Adaptive Design in Clinical Trials
Jie Tang, Pfizer

101 Model selection and its application in clinical trial design
Qi Jiang, Amgen Inc.

Break

Parallel Sessions

1 Law and Statistics
Gang Zheng, NHLBI

4 Stochastic root-finding and optimization
Hock Peng Chan & Inchi Hu, NUS(Singapore)

12 Functional data analysis
Dawei Liu & Ying Zhang, Univ. of Iowa

34 High-Dimensional Inference in Biostatistical Applications
Jessie Jeng, Upenn

37 Statistical Machine Learning
Ji Zhu, Univ. of Michigan

43 Adaptive Designs post-FDA guidance: Challenges and solutions
Jose Pinheiro, Johnson & Johnson

49 Spatial Statistics in Bio-medical applications
Ji Meng Loh, AT&T Labs-Research

50 Nonparametric Inference and Secondary Analysis in Genomwide Studies
Yongzhao Shao, NYU

88 Next Generation Pharmacovigilance: methodological and policy challenges
Zhezhen Jin, Columbia Univ.

91 Statistics in Drug Discovery and Early Development
Donghui Zhang, sanofi-aventis

Social Program: Cruise

Tuesday (June 28th, 2011)

8:45 AM -9:45 AM  Keynote lecture
Danyu Lin, UNC-Chapel Hill

9:45 AM -10:00 AM  Break

10:00AM-11:40 AM  Parallel sessions

6 Recent Development in Multivariate Survival Data Analysis
Wenqing He, Univ. of Western Ontario

24 Interface between nonparametric and semiparametric analysis and genetic epidemiology
Yuanjia Wang & Naihua Duan, Columbia Univ.
25 High Dimensional Statistics in Genomics  
Hongzhe Li, Upenn

53 Applications in spatial statistics  
Zhengyuan Zhu, Iowa State Univ.

61 The totality of evidence in drug safety and efficacy evaluation  
Qian Li & Greg Soon, FDA

65 Estimating Treatment Effects in Randomized Clinical Trials with Non-compliance and Missing Outcomes  
Greg Soon & Yan Zhou, FDA

67 Analysis of biased survival data  
Xiaodong Luo, Mount Sinai School of Medicine

69 Suicide Research Methodology  
Naihua Duan, Columbia Univ.

92 Joint Modeling of Longitudinal and Time-to-Event Data in Medical Research  
Wei Shen, Eli Lilly and Company

94 Survey research method and its application in public health  
Huilin Li, New York Univ.

11:40 AM - 1:30 PM  
Lunch break

1:30 PM - 3:10 PM  
Parallel sessions

10 Seiparametric models with application in biosciences  
Hua Liang & Dacheng Liu, Univ. of Rochester

26 Statistical Methods for Analysis of Next Generation Sequences Data  
Hongzhe Li, Univ. of Pennsylvania

32 Network and related topics  
Jiashun Jin, Carnegie Mellon Univ.

46 Recent Developments in Design and Analysis for High-dimensional Data  
Sijian Wang, Univ. of Wisconsin

62 Current Approaches for Pharmaceutical Benefit-Risk Assessment  
Bennett Levitan, Johnson & Johnson

64 Causal Inference and its applications in drug development  
Greg Soon & Thamban Valappil, FDA

74 Recent advance in multiplicity approach  
David Li & Chunming (Mark) Li, Pfizer

76 Bioassay: Methodology for A Rapidly Developing Area  
Xuelin Huang, MD Anderson Cancer Center

80 Statistical Challenges in Developing Biologics  
Jason J.Z. Liao & Guoxing (Greg) Soon, Teva Branded Pharmaceutical Products R&D, Inc.

85 Experimental Design and clinical trials  
Changxin Ma, SUNY-Buffalo

95 Advancing Clinical Trial Methods  
Daniel F. Heitjan, Upenn

98 Panel Session: Adaptive Designs – When Can and How Do We Get There From Here?  
Yeh-Fong Chen, FDA

3:10 PM - 3:30 PM  
Break

3:30 PM - 5:10 PM  
Parallel sessions

9 Statistical Analysis on spatial and temporal data  
Minggen Lu, Univ. of Nevada, Reno

14 Recent Developments in Methods for Handling Missing Data  
Thomas R. Belin, UCLA

18 Methodology for and Applications of Administrative Data  
Rhonda Rosychuk, Univ. of Alberta

27 Fiducial inference, generalized inference, and applications  
Lili Tian, SUNY-Buffalo

31 Functional data analysis  
Hong-Bin Fang, PhD., Univ. of Maryland

33 Statistical Method and Theory for High-dimensional Data  
Zhigen Zhao, Temple Univ. & Jiashun Jin, CMU
42 Statistical Genomics
70 Assessment of blinding and placebo effect
71 Recent Advances in Survival Analysis and Clinical Trials
78 Biomarker based adaptive design and analysis for targeted agent development
86 Analysis of Complex data
90 Historical Insight on Statisticians Role in the Pharmaceutical Development
96 Handling Heaping

6:30 PM - 8:30 PM * Banquet

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Wednesday (June 29th, 2011)

8:45 AM - 10:25 AM parallel sessions
7 Statistical Methods for Disease Genetics and Genomics
8 Enhancing clinical development efficiency with adaptive decision making
15 Multivariate and Subgroup Analysis
19 Statistical Issues Arised from Clinical Research
29 Recent developments in modeling data with informative cluster size
38 New Developments in High Dimensional Variable Selection
39 Model selection and related topics
45 Empirical likelihood and its application
75 Design and Analysis Issues in DNA methylation
77 Recent advances in statistical inference for functional and longitudinal data
83 Emerging statistical methods and theories for complex and large data
93 Complex multivariate outcomes in biomedical science

10:25 AM - 10:45 AM break

10:45 AM - 12:25 PM parallel sessions
16 Recent development in measurement error models
23 Recent Developments in Time Series
28 Challenging topics in longitudinal data
40 High-dimensional models
41 Phase I/II clinical studies: safety versus efficacy
48 Network analysis
57 Recent advances in genome-wide association studies

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Organizer(s)
Yu Zhang, Penn. State Univ.
Weili He & Cong Chen, Merck & Co., Inc.
Kelly H. Zou, Pfizer Inc.
Nan Xue, Albert Einstein College of Medicine
Zhen Chen, NICHD/NIH
Jinchi Lv, Univ. of Southern California & Ji Zhu
Yichao Wu, NCSU & Mengling Liu, NYU
Wenqing He, Univ. of Western Ontario
Shuang Wang, Columbia Univ.
Lijian Yang, Michigan State Univ.
Minge Xie, Rutgers Univ.
Eva Petkova, New York Univ.

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23 Recent Developments in Time Series
28 Challenging topics in longitudinal data
40 High-dimensional models
41 Phase I/II clinical studies: safety versus efficacy
48 Network analysis
57 Recent advances in genome-wide association studies

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Organizer(s)
Yanyuan Ma, Texas A&M
Zhibiao Zhao, Penn. State Univ.
Annie Qu, UIUC
Xiaotong Shen, Univ. of Minnesota
Bin Cheng, Columbia Univ.
Tian Zheng & Tyler McCormick, Columbia Univ.
Hongyu Zhao, Yale Univ.
<table>
<thead>
<tr>
<th>58</th>
<th>Statistical methodology and regulatory issues in drug development in multiple regions</th>
<th>David Zhang, GeneTech</th>
</tr>
</thead>
<tbody>
<tr>
<td>81</td>
<td>Genomic Biomarker Applications in Clinical Studies</td>
<td>Zhaoling Meng, Sanofi Avertis</td>
</tr>
<tr>
<td>89</td>
<td>Statistical Modeling and Application in System Biology</td>
<td>Wenxuan Zhong, UIUC</td>
</tr>
<tr>
<td>100</td>
<td>Statistical Methodologies</td>
<td>Gang Li, Johnson &amp; Johnson, PRDUS</td>
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* exact time to be confirmed