華東師範大學
EAST CHINA NORMAL UNIVERSITY

上海生物统计学术论坛
SBF

2012 International Pharmaceutical Statistics Workshop (IPSW)

July 10 – July 12, 2012 • Shanghai • China

Third Announcement (May, 2012)

The growing trend of global clinical drug development demands increasing number of biometrics-related professionals (biostatisticians, clinical programmers and clinical database professional) across the globe. This trend is most noticeably reflected in the establishment of biometrics centers in China by world's major pharmaceutical companies, and newly established division of biostatistics in the SFDA.

To promote biopharmaceutical statistics education and profession, the 2012 International Pharmaceutical Statistics Workshop (IPSW) will be hosted by Academy of Applied Statistical Science, East China Normal University (ECNU) and Shanghai Biostatistics Forum (SBF) from July 10 to July 12, 2012.

Other institutional sponsors for this event include:

China Applied Statistics Association, Survival Analysis Society
Duke University, Department of Biostatistics and Bioinformatics
Hong Kong Baptist University, Statistics Research and Consultancy Centre
International Chinese Statistical Association
International Society of Biopharmaceutical Statistics
Shanghai Institute of Pharmaceutical Industry
University of Wisconsin-Madison, Department of Statistics

For updated information, please visit workshop website: http://www.sfs.ecnu.edu.cn/2012IPSW/IPSW2012.html .

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Invited Keynote Speakers

Dr Michael Kosorok	Professor and Chair, Department of Biostatistics, University of North Carolina at Chapel Hill
Dr Bob O'Neill	Director, Office of Biostatistics, CDER, FDA

Invited Speakers (partial list)

Dr Frank Bretz	Global Head of Statistical Methodology, Novartis Pharma AG and Adjunct Professors at Hannover Medical School and SHUFE
Dr Ivan S.F. Chan	Senior Director, Late Development Statistics, Merck & Co, Inc. and President, International Chinese Statistical Association
Dr Shein-Chung Chow	Professor, Department of Biostatistics, Duke University
Dr Chinfu Hsiao	Director, Clinical Trial Center, National Health Research Institutes, Taiwan
Dr Chao Agnes Hsiung	Distinguished Investigator and Director, Division of Biostatistics and Bioinformatics, National Health Research Institutes, Taiwan
Dr Byron Jones	Biometrical Fellow, Novartis Pharma AG and Visiting Professor of Statistics at University College London
Dr Gordon Lan	Senior Director of QDS, Janssen R&D, Johnson & Johnson
Dr Guohua Pan	Director, Clinical Biostatistics, Janssen R&D, Johnson & Johnson
Dr Claude Petit	Executive Director of Biostatistics, Boehringer Ingelheim, USA
Dr Stephen Ruberg	Distinguished Research Fellow, Eli Lilly and Company
Dr Stephen Senn	Head of Unit, Competence Center for Methodology and Statistics, CRP-Santé, Luxembourg
Dr Yi Tsong	Deputy Director of Division of Biometrics VI, CDER, FDA
Dr Yue Wang	Head of Quantitative Biology, BeiGene
Dr Jielai Xia	Professor, The Fourth Military Medical University
Dr Chen Yao	Professor and Head of Department of Biostatistics, Peking University First Hospital
Dr Kwee Poo Yeo	Senior Research Scientist, Eli Lilly and Company
Dr Heping Zhang	Professor, School of Public Health, Yale University
Dr Peng-Liang Zhao	Head of Biostatistics & Programming in China, Sanofi
Dr Bob Zhong	Associate Director, Janssen R&D, Johnson & Johnson

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Program

Short Courses (July 10, 2012)

SC-I	'Adaptive design' Dr Shein-Chung Chow, Professor, Department of Biostatistics and Bioinformatics, Duke University
SC-II	'Non-inferiority trial' Dr Yi Tsong, CDER, FDA
SC-III	'Meta analysis' Dr Byron Jones, Biometrical Fellow, Novartis Pharma AG

Workshop (July 11 – July 12, 2012)

Sessions

- Survival trial and oncology
- Early development and genetic statistics
- Personalized medicine and biomarker
- Biosimilarity
- Noninferiority trial
- Adaptive design
- Statistical programming
- Clinical data management
- Multi-regional clinical trial
- Pharamco-vigillance and pharmaco-epidemiology
- Bayes statistics and medical device
- Independent data monitoring committee
- Regulatory statistics (panel discussion)
- Biostatistics education and career promotion (panel discussion)

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Venue

Jianguo Hotel Shanghai (439 North Caoxi Road, Shanghai 200030) www.jianguo.com

Registration

Domestic attendees: please send the *registration form* to ipsw2012@gmail.com and send the *hotel reservation form* to simongaolei@yahoo.com.cn

International attendees: please register at www.isbiostat.org/ipsw2012/

Fee schedule

Domestic	Before May 1, 2012		On/After May 1, 2012	
	Short Courses (July 10, 2012)			
	Half day	Full day	Half day	Full day
Student	250RMB	400RMB	300RMB	500RMB
Non-student	500RMB	800RMB	600RMB	1000RMB
	Fees include tea break.			
	Workshop (July 11-12, 2012)			
Student	500RMB		600RMB	
Non-student	1000RMB		1200RMB	
	Fees include tea break, lunch buffet, and banquet. 200RMB/additional guest for banquet			

International	Before May 1, 2012		On/After May 1, 2012	
	Short Courses (July 10, 2012)			
	Half day	Full day	Half day	Full day
Student	50USD	80USD	60USD	100USD
Non-student	100USD	160USD	120USD	200USD
	Fees include tea break.			
	Workshop (July 11-12, 2012)			
Student	100USD		120USD	
Non-student	200USD		240USD	
	Fees include tea break, lunch buffet, and banquet. 40USD/additional guest for banquet			

Cancellations Policy:

All cancellations must be submitted in writing through email: ipsw2012@isbiostat.org (for international) and ipsw2012@gmail.com (for domestic). Cancellation received on/before June 9, 2012: Conference registration will be refunded less a $20 (130RMB for domestic) processing fee. Short courses will be refunded less $20 (130RMB for domestic) per course. Cancellations received after June 9, 2012 but on/before July 1: 50% of registration fee for the conference and the short courses will be refunded. Cancellations received after July 1: No refund will be issued. Registrants who do not submit cancellation on or before July 1 will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. If the event is cancelled, the organization is not responsible for airfare, hotel or other costs incurred by the registrant.

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Steering committee:

Shein-Chung Chow (Duke)
Qin Huang (SFDA)
Jun Shao (ECNU)
William Wang (Merck)
Naiqing Zhao (Fudan)

Program committee:

Co-chairs:
Jun Shao (ECNU), William Wang (Merck), Naiqing Zhao (Fudan)

Committee Members:
Shein-Chung Chow (Duke)
Jia He (SMMU)
Xiaoyin Fan (Vertex)
Jacqueline Law (Roche)
Minzhi Liu (MacroStat)
Changxuan Mao (SHUFE)
Robert Luo (Pfizer)
Dejun Tang (Novartis)
Wenjin Wang (Pfizer)
Jin Xu (ECNU)
Chen Yao (PKU)
Bingming Yi (GSK)
Weiying Yuan (Johnson & Johnson)
Wei Zhang (Boehringer Ingelheim)
Shuping Zhang (Merck)
Zibao Zhang (PPD**)**
Pengliang Zhao (Sanofi-Aventis)

Local Organizing Committee:

Jun Shao (ECNU)
Naiqing Zhao (Fudan)
Jin Xu (ECNU)
Yingchun Zhou (ECNU)
Hekun Xu (ECNU)

Contact us

Address: Academy of Applied Statistical Science, East China Normal University, 500 Dongchuan Road, Shanghai 200241
Email: ipsw2012@gmail.com; yczhou@stat.ecnu.edu.cn (Dr Yingchun Zhou)
Tel/Fax: 86-21-54345058

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Program Outline

Day One: Tuesday, July 10, 2012		
8:00 – 21:00	**Registration**	
8:30 – 12:00	**Short Course I: Adaptive design** Dr Shein-Chung Chow, Duke University	
12:00 – 13:30	**Luncheon**	
14:00 – 17:30	**Short Course II: Non-inferiority trial** Dr Yi Tsong, CDER, FDA	**Short Course III: Meta analysis** Dr Byron Jones, Novartis

Day Two: Wednesday, July 11, 2012		
8:00 – 11:30	**Registration**	
8:30 - 9:00	**Opening Remarks**	
9:00 – 10:00	**Plenary-I: The Science of Regulatory Statistics: A Perspective on its Growth and Impact** Organizer and Chair: Shein-Chung Chow (Duke) Bob O'Neill (FDA)	
10:00 – 10:20	**Tea Break**	
10:20 – 11:50	**Parallel 1: Biosimilarity** Organizers and Chairs: Shein-Chung Chow (Duke) • Regulatory requirements for assessment of biosimilar products – Dr Chinfu Hsiao, Director, Clinical Trial Center, National Health Research Institutes, Taiwan • Some statistical issues on the evaluation of the similarity and interchangeability of biologics – Dr Laszlo Endrenyi, U. of Toronto • Scientific factors for assessing biosimilarity and interchangeability of follow-on biologics – Dr Shein-Chung Chow, Professor, Duke U.	**Parallel 2: IDMC** Organizers and Chairs: Irving Hwang (ICG), Yingchun Zhou (ECNU) • Interim analysis and design of clinical trials – Dr Kuang-Kuo Gordon Lan, Senior Director, Janssen R&D, Johnson & Johnson, • Experience in multicenter oncology trials in Taiwan – Dr Chao Agnes Hsiung, National Health Research Institute, Taiwan • Practice of DMCs in clinical trials in China – Dr Chen Yao, Professor, Peking University Clinical Research Institute
12:00 – 13:30	**Luncheon**	

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Day Two: Wednesday, July 11, 2012		
13:30 – 15:00	**Parallel 3: Personalized medicine and biomarker** Organizer and Chair: Robert Luo (Pfizer), Minzhi Liu (MacroStat) • Statistical considerations during the discovery and development of patient selection biomarkers – Dr Yue Wang, Head of Quantitative Biology, BeiGene • Finding the right patients considerations for developing tailored therapeutics – Dr Steven J. Ruberg, Distinguished Research Fellow, Eli Lilly & Company • Zelboraf for unresectable or metastatic melanoma with the BRAF V600 mutation: Clinical development of a targeted therapy – Betty Nelson, Principal Statistical Scientist, Roche/Genentech	**Parallel 4: Decision-making and scientific programming** Organizer and Chair: Shuping Zhang (Merck) • Decision-making in post clinical trials – Dr Heping Zhang, Professor, Yale University • Alternative imputation method using SAS – Dr Xingshu Zhu, Merck Inc. • Collaboration between China and Japanese pharmaceutical industry – Dr Masato Suzuke, Japan Merck – KK
15:00 – 15:20	**Tea Break**	
15:20 – 16:50	**Parallel 5: Early development statistics** Organizer and Chair: Bingming Yi (GSK) • Statisticians and pharmacological modellers: collaboration is the key to success – Dr Stephen Senn, Head of Unit, Competence Center for Methodology and Statistics, CRP-Santé, Luxembourg • Critical success factors for early phase drug development – Dr Kwee Poo YEO, Senior Research Scientist, Eli Lilly and Company • On the time to conclusion of Phase II cancer clinical trials and its application in trial designs – Dr Ying Lu, Professor, Stanford University	**Parallel 6: Clinical data management** Organizers and Chairs: Zibao Zhang (PPD) • China clinical data management regulatory updates – Dr Qin Huang, Office of Biostatistics, China SFDA/CDE • CDM role in the FDA guidance of risk-based approach to monitoring – Joan Huang, Clinical Data Service, Pfizer CRDC • Opportunities and challenges in clinical data management – Robert Robinson, Life Sciences BPO – China Cognizant

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17:00 – 18:30 (refreshment served)	**Panel discussion: Regulatory statistics** Organizer and Chair: Bill Wang (Merck) Qin Huang (SFDA), Bob O'Neill (FDA),Yi Tsong (FDA), Chen Yao (PKU), Toshimitsu Hamasaki (Osaka U), Shein-Chung Chow (Duke)
18:30- 20:00	**Banquet**

Day Three: Thursday, July 12, 2012		
8:30 – 10:00	**Parallel 7: Survival trial and Oncology** Organizer and Chair: Weiying Yuan (J&J), Changxuan Mao (SHUFE) • Survival data analysis – Kuang-Kuo Gordon Lan, Senior Director, Janssen R&D, Johnson & Johnson • Analyses of time-to-event data in the NDA of Rivaroxaban for atrial fibrillation – Dr Guohua (James) Pan, Director, Janssen R&D, Johnson & Johnson • Statistical Power in Stratified or Covariate-Adjusted Failure Time Data Analyses – Dr Jianliang Zhang, MedImmune	**Parallel 8: Adaptive design** Organizer and Chair: Jin Xu (ECNU) and Linda Sun (Merck) • On the efficiency of two-stage response-adaptive – Dr Frank Brets, Novartis • The advantageous adaptive randomization in clinical trials – Dr Bob Zhong, Janssen Pharmaceuticals, Johnson & Johnson • Improving vaccine clinical development using adaptive design strategies – Dr Ivan S.F. Chan, Senor director, Merck
10:00 – 10:20	**Tea Break**	
10:20 – 11:50	**Parallel 9: Non-inferiority trial** Organizer and Chair: Wei Zhang (BI) and Jia He (SMMU) • Comparing the response rates for superiority, non-inferiority and equivalence testing with multiple-to-one matched binary endpoint – Yi Tsong, CDER, FDA • What did we learn from the most recent FDA advisory committees when reviewing non inferiority trials? – Claude Petit, Boehringer Ingelheim • The statistical consensus of non-inferiority clinical trial for NDA in China – Jielai Xia, The 4th Military Medical U.	**Parallel 10: Bayes statistics and Medical device** Organizer and Chair: Dejun Tang (Novartis) • Examples of the use of Bayesian methods in the pharmaceutical industry – Dr Byron Jones, Novartis Pharma AG • Bayesian adaptive designs for early-phase oncology trials – Dr Guosheng Yin, HongKong U. • Bayesian applications in medical regulations in the US – Yao Huang, FDA
12:00 – 13:30	**Luncheon**	

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Day Three: Thursday, July 12, 2012		
13:30 – 15:00	**Parallel 11: Multi-regional clinical trial** Organizer and Chair: Pengliang Zhao (Sanofi), Jacqueline Law (Roche) • Design considerations for simultaneous global drug development – Dr Gang Chen, Johnson and Johnson • Practical issues and lessons leaned from HERA and ToGA trials conducted in Japan as part of multi-regional Clinical Trials – Hideharu Yamamoto, Chugai Pharmaceutical • Empirical shrinkage estimator for consistency assessment of treatment effects in multi-regional clinical trials – Dr Peng-Liang Zhao, Sanofi	**Parallel 12: Pharamco-vigillance and Pharmaco-epidemiology** Organizer and Chair: Wei Zhou (Merck) Bill Wang (Merck) • Pharmacoepidemiology perspectives of CER – Dr Jay Pearson, Merck • Prior event rate ratio (PERR) adjustment for unrecognized confounding in observational studies – Dr Menggang Yu, U. of Wisconsin-Madison • Sequential generalized likelihood ratio tests for safety evaluation – Dr Jie Chen, Merck Serono
15:00 – 15:20	**Tea Break**	
15:20 – 16:20	**Plenary-II: Personalized Medicine and Statistical Learning** Organizers: Jun Shao (ECNU) Michael Kosorok (Department of Biostatistics, UNC)	
16:30 – 18:00 (refreshment served)	**Panel discussion: Biostatistics education and career promotion** Organizers: Naiqing Zhao (Fudan) and Jin Xu (ECNU) Michael Kosorok (UNC), Ivan S. F. Chan (Merck), Stephen Senn, Jun Shao (ECNU),	
18:00 – 18:05	**Closing Remarks**	