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)

国际医药统计研讨会

7 月 10 日 – 7 月 12 日 • 上海

第三次通知（2012 年 5 月）

全球临床医学的快速发展对与生物计量相关的专业人员（包括生物统计师，临床程序员和临床数据管理人员）提出人数和技术上的更多的需求。世界主要的医药公司都在中国设立了生物计量中心，中国食品药品管理局也新成立了生物统计部门，这些都明显地反映出了这一发展趋势。

为了促进生物统计的专业教育培训和行业发展，华东师范大学应用统计科学学院将联合上海生物统计论坛于 2012 年 7 月 10 日－7 月 12 日举办 2012 国际医药统计研讨会。

其他协办单位包括：

中国现场统计学会，生存分析分会
杜克大学生物统计学和生物信息学系
香港浸会大学统计研究咨询中心
泛华统计协会 （International Chinese Statistical Association）
国际生物制药协会（International Society of Biopharmaceutical Statistics）
上海医药工业研究院（Shanghai Institute of Pharmaceutical Industry）
美国威斯康星大学统计系

了解最新更新信息，请访问会议主页http://www.sfs.ecnu.edu.cn/2012IPSW/IPSW2012.html 。

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主题发言人

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

邀请发言人（部分）

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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会议日程

短课程 （2012 年 7 月 10 日）

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

研讨会（2012 年 7 月 11 日－12 日）

主题

- 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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地点

上海建国宾馆 (上海市漕溪北路 439 号, 200030) www.jianguo.com

注册

国内参会人员： 请发送*注册表*到 ipsw2012@gmail.com
发送*宾馆预订表*到 simongaolei@yahoo.com.cn

国际参会人员： 请在 www.isbiostat.org/ipsw2012/ 直接注册

会议收费表

国内	2012 年 5 月 1 日之前		2012 年 5 月 1 日之后	
	短课程 (2012 年 7 月 10 日)			
	半天	一天	半天	一天
学生	250 元	400 元	300 元	500 元
非学生	500 元	800 元	600 元	1000 元
	含茶歇			
	研讨会 (2012 年 7 月 11 日－12 日)			
学生	500 元		600 元	
非学生	1000 元		1200 元	
	含茶歇，自助午餐和晚宴；晚宴客人每人 200 元			

国际	2012 年 5 月 1 日之前		2012 年 5 月 1 日之后	
	短课程 (2012 年 7 月 10 日)			
	半天	半天	半天	半天
学生	50 美元	80 美元	60 美元	100 美元
非学生	100 美元	160 美元	120 美元	200 美元
	含茶歇			
	研讨会 (2012 年 7 月 11 日－12 日)			
学生	100 美元		120 美元	
非学生	200 美元		240 美元	
	含茶歇，自助午餐和晚宴；晚宴客人每人 40 美元			

取消注册:

取消注册须发电子邮件至ipsw2012@isbiostat.org (国际) 或 ipsw2012@gmail.com (国内)。 2012 年 6 月 9 日前取消：退还会议注册费扣除 20 美元(人民币 130 元)手续费的部分，退还短课程注册费每门扣除 20 美元(人民币 130 元)的部分。 2012 年 6 月 9 日之后，7 月 1 日之前取消：退还 50% 会议注册费和 50%短课程注册费。7 月 1 日之后取消：无退款。注册者应自行负责取消宾馆预订。如果研讨会取消，主办方不负责已经发生的旅费，住宿费和其他费用。

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指导委员会：

Shein-Chung Chow (Duke)
黄钦(中国食品药品管理局)
邵军 (华东师范大学)
William Wang (Merck)
赵耐青 (复旦大学)

会议程序委员会：

主席：

邵军（华东师范大学），William Wang （Merck），赵耐青（复旦大学）

成员：

Shein-Chung Chow (Duke)
贺佳 (第二军医大学)
Xiaoyin Fan (Vertex)
Jacqueline Law (Roche)
Minzhi Liu (MacroStat)
茆长暄 (上海财经大学)
Robert Luo (Pfizer)
Dejun Tang (Novartis)
Wenjin Wang (Pfizer)
徐进 (华东师范大学)
姚晨 (北京大学)
Bingming Yi (GSK)
Weiying Yuan (Johnson & Johnson)
Wei Zhang (Boehringer Ingelheim)
Shuping Zhang (Merck)
Zibao Zhang (PPD)
Pengliang Zhao (Sanofi-Aventis)

会议组织委员会：

邵军（华东师范大学）
赵耐青（复旦大学）
徐进（华东师范大学）
周迎春（华东师范大学）
徐和坤（华东师范大学）

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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**	