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DRUG INFORMATION ASSOCIATION

The First DIA Training Workshop in China

Understanding the Statistical Thinking in Clinical Research for Drug Development

MAY 11-12, 2009 | **Hotel Equatorial, Shanghai, China**

CHAIRPERSON

LINGSHI TAN, PhD
General Manager
Pfizer (China) Research and Development Co., Ltd., China

PROGRAM COMMITTEE

IRVING HWANG, PhD
President, Irving Consulting Group (ICG), USA
Adjunct Professor, University of Medicine & Dentistry of New Jersey, USA
Visiting Professor, Health Statistics, Second Military Medical University, Shanghai, China

ROGER QU, PhD
Head of Statistics Department
Pfizer (China) Research and Development Co., Ltd., China

FRANK SHEN, PhD
Head of Biometrics and Clinical Study Management
Roche Pharma Development Center in China, China

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WILLIAM WANG, PhD
Head of China Operations, Department of Biostatistics and Research Decision Sciences, Merck Research Laboratories, Merck & Co., Inc., China

WEIYING YUAN, PhD
Site Head of Biostatistics and Clinical Informatics in Asia
Johnson and Johnson Pharmaceutical Research and Development, China

ABOUT THE WORKSHOP

Built on an overview of fundamental statistical concepts, this 2-day training workshop is designed as an in-depth, practical, basic- to intermediate-level introduction to selected clinical research designs and statistical methodologies, for drug research and development professionals who have regular exposure to statistics either through studies or professional experience.

This workshop introduces the essentials of statistical principles and emphasizes their application to clinical investigation to help participants understand the statistical thinking in these clinical trial designs and analyses. This workshop will specifically focus on oncology trials and noninferiority/equivalence designs.

WHO WILL ATTEND

This workshop will particularly benefit professionals who must understand and work with statistical concepts related to clinical research and development, including but not limited to:

- Clinical research operations
- Clinical science
- Regulatory affairs
- Project management
- Data management and biostatistics

LEARNING OBJECTIVES

At the conclusion of the workshop, participants should be able to:

- Comprehend basic statistical concepts and practical aspects discussed in this workshop
- Recognize critical statistical issues in design and analysis of oncology trials
- Understand how to establish noninferiority or equivalence
- Work closely with statistical professionals

DIA, 800 Enterprise Road, Suite 200, Horsham, PA 19044, USA tel: +1-215-442-6100 fax: +1-215-442-6199 email: dia@diahome.org

MONDAY • MAY 11, 2009

7:30-8:30 REGISTRATION

8:30-8:40 CHAIRPERSON'S OPENING REMARKS

Lingshi Tan, PhD
General Manager, Pfizer (China) Research and Development Co., Ltd., China

8:40-10:40 SESSION 1

Practical Aspects of Biostatistics

CHAIRPERSON

Frank Shen, PhD
Head of Biometrics and Clinical Study Management
Roche Pharma Development Center in China, China

The objective of this session is to provide a brief review of basic statistical concepts and methodologies, particularly those most related to the topics covered in this workshop.

- Evidence-based medicine is statistically based
- Type I and Type II errors
- Sample size estimation
- Prospective vs. retrospective analyses
- Multiplicity and interim analysis
- Survival guide for survival analysis

10:40-11:00 REFRESHMENT BREAK

11:00-12:30 SESSION 2

Statistical Methods for Oncology Clinical Trials – *Part 1*

CHAIRPERSON

Roger Qu, PhD
Head of Statistics Department
Pfizer (China) Research and Development Co., Ltd., China

Oncology is one of the most active areas in new drug clinical research and development. The design, conduct and analysis of oncology trials present many unique features and challenges to clinical trialists and other professionals in drug development. This session will provide a comprehensive coverage of common statistical analyses and outcomes in oncology clinical trials, followed by real-world case studies.

- Study designs
- Efficacy endpoints
- Summarization of clinical data
- Statistical inferences
- Treatment comparisons

12:30-13:45 LUNCHEON

13:45-15:30 SESSION 2 *continued*

Statistical Methods for Oncology Clinical Trials – *Part 1* *continued*

15:30-16:00 REFRESHMENT BREAK

16:00-17:00 SESSION 2 *continued*

Statistical Methods for Oncology Clinical Trials – *Part 2:* Case Studies – Development of an Oncology Product

CHAIRPERSON

Irving Hwang, PhD
President, Irving Consulting Group (ICG), USA; Adjunct Professor, University of Medicine & Dentistry of New Jersey, USA
Visiting Professor, Health Statistics, Second Military Medical University, Shanghai, China

17:30-19:00 NETWORKING RECEPTION

TUESDAY • MAY 12, 2009

7:30-8:30 REGISTRATION

8:30-10:00 SESSION 3

Noninferiority and Equivalence Trials

CHAIRPERSONS

Irving Hwang, PhD

William Wang, PhD
Head of China Operations, Department of Biostatistics and Research Decision Sciences, Merck Research Laboratories, Merck & Co., Inc., China

Weiying Yuan, PhD
Site Head of Biostatistics and Clinical Informatics in Asia
Johnson and Johnson Pharmaceutical Research and Development, China

There has been a steady increase in the use of active control trials to investigate the efficacy and safety of a new investigational regimen. In this session, we will focus on those active control trials where the primary objective is to demonstrate that a new regimen is not inferior to an active control. We will review fundamental concepts and practice that are required to ensure that such trials can accomplish the research objectives. Three real-world case studies will follow.

Design, Analysis and Inference: Concepts and Practice

- ICH E10 guidance – Choice of control groups
- Superiority vs. noninferiority/equivalence trials
- Assay sensitivity (AS) and constancy assumption (CA)
- Noninferiority margin and fraction of control effect preservation
- Sample size and power consideration
- Noninferiority inference
- Evaluation objectives/Switching objectives
- Regulatory and operational challenges
- Useful alternatives

10:00-10:30 REFRESHMENT BREAK

10:30-12:00 SESSION 3 *continued*

Noninferiority and Equivalence Trials *continued*

12:00-13:15 LUNCHEON

13:15-15:30 SESSION 3 *continued*

Noninferiority and Equivalence Trials: Noninferiority Trial Case Studies

- Evaluation of GI safety in the development of a product for rheumatoid arthritis
- Development of an antidiabetic therapy
- Development of an oncology product (Part 2)

15:30-16:00 REFRESHMENT BREAK

16:00-17:30 SESSION 4

Panel Discussion – Q & A

All speakers

17:30 CHAIRPERSON'S CLOSING REMARKS

Lingshi Tan, PhD
General Manager, Pfizer (China) Research and Development Co., Ltd., China

WORKSHOP ADJOURNED

About the Speakers

Lingshi Tan, PhD

Dr. Lingshi Tan is the founder and General Manager of Pfizer (China) Research and Development Co., Ltd., which was established in Shanghai in 2005. Prior to his current role, Dr. Tan was the Head of Biometrics for Pfizer's Japan/Asia, Africa, Middle East, and Latin America regions since 2001. His achievement in this capacity is highlighted by setting up and managing Biometrics centers, including the Asia Biometrics Center in Sydney in 2002 and the Latin America Biometrics Center in New York in 2004. Dr. Tan joined Pfizer Inc. of New York in 1996, following biostatistical positions at Children's Hospital of Pittsburgh and Schering-Plough Research Institute of New Jersey. Dr. Tan has led a number of projects in China since 1999. He has 16 years of pharmaceutical industry experience. His publications and presentations cover both theoretical statistics and clinical studies. Dr. Tan holds a Master's degree in Applied Mathematics and a PhD in Biostatistics, both from the University of Pittsburgh. Dr. Tan serves on the Advisory Board for the Graduate Program in International Pharmaceutical Engineering Management at Peking University and the Advisory Board at the School of Pharmacy of Fudan University, respectively.

Irving K. Hwang, PhD

Dr. Irving Hwang is currently President, Irving Consulting Group (ICG); Adjunct Professor, University of Medicine & Dentistry of New Jersey (UMDNJ); and Visiting Professor, Health Statistics, Second Military Medical University (SMMU), Shanghai, PRC. Previously, Dr. Hwang was Senior Vice President, Harvard Clinical Research Institute; Vice President and Head, Global Biometrics, Hoechst Marion Roussel, Inc.; and Senior Director, Clinical Biostatistics and Research Data Systems, Merck. He was formerly PhRMA Deputy Topic Leader, ICH E10 Expert Working Group.

Dr. Hwang has over a quarter century of global drug development experience with major pharmaceutical and biotech companies in design and analysis of clinical trials for development of new drugs and vaccines. He has hands-on experiences in many successful NDAs/BLAs and EU registrations (MAAs). He specializes in high-level biostatistical consulting in global new drug development. He consults on statistical methodologies in clinical trials including design and analysis of exploratory, confirmatory, adaptive, and active-control trials. He provides statistical trouble-shooting and resolution for client companies. He also participates in the independent data monitoring committees (IDMCs) as chair/member.

Dr. Hwang received his PhD in Statistics from the Wharton School, University of Pennsylvania. He had taught graduate courses – biostatistics in clinical trials at Rutgers and UMDNJ. He had also given lectures at SMMU, Fudan University, and Jiaotong University. Dr. Hwang has many professional publications, presentations, and lectures in statistics and clinical trial applications including DIA, ICSA, and SFDA tutorials.

Roger Qu, PhD

Roger Qu, PhD, is Head of the Statistics Department of Pfizer China Research and Development Center, where he leads a team of statisticians providing statistical support to Pfizer in both global and regional clinical trials in drug development.

Prior to joining Pfizer, Roger took various positions at Hoechst Marion Roussel, R.W. Johnson Pharmaceutical Research Institute and Forest Laboratories, Inc. During his more than ten-year industrial career, he has taken various positions with increasing responsibilities starting from study statistician to Senior Director of Biostatistics at Forest Laboratories, Inc. He has led statistical teams supporting clinical development and regulatory submissions across a range of important therapeutic areas including CV, GI, Pain and Respiratory.

Roger's statistical interest focuses on clinical statistics such as analysis of longitudinal data and missing data, multiple comparison procedures, group sequential analysis, and survival analysis. He had numerous statistical publications and was lead author for publications in statistical journals including *Biometrics, Statistica Sinica, Statistics and Probability Letters, Communications in Statistics*, and *Controlled Clinical Trials*.

Roger holds a PhD degree in Statistics from the University of Wisconsin at Madison, and a Bachelor's degree in Mathematics from East China Normal University, Shanghai, China.

Frank Shen, PhD

Dr. Shen is currently the Head of Biometrics and Clinical Study Management for Roche Pharma Development Center in China. Prior to joining Roche, Frank was the Executive Director of Global Biometric Sciences, Bristol-Myers Squibb (BMS). In that role, he led a group of 80 biostatisticians, statistical geneticists, programmers, and data managers with a mission to accelerate quality drug development by integrating data flow and statistical collaborations into drug discovery, early clinical development, pharmacogenomics, and pharmacovigilance through close partnerships with scientists. Frank was also a member of the BMS Clinical Science Committee and the Development Excellence Council that review clinical protocols and govern processes in clinical operations. Frank was the BMS Asia Pacific liaison from 2003 to 2007 to focus global biometric integration in Japan, China and India.

Frank joined the pharmaceutical industry in 1989 and worked at Wyeth-Ayerst Research as a Research Statistician until 1993 and then joined the Biometrics Research group at Merck & Co. as a manager. He joined BMS in 1996 as Associate Director and progressed with increasing responsibilities.

Frank received his BS and MS degrees in Chemical Engineering from Chung-Yuan University, Taiwan, and Lamar University, Texas, respectively, and a PhD in Statistics from Temple University. He has focused his career pursuits in the areas of biostatistics, drug development, and clinical trial designs and operations.

Frank was named a Fellow of the American Statistical Association in 2003, and elected as the 2004 President of the International Chinese Statistical Association (ICSA). Frank was a member of the Clinical Leadership Committee (CLC) of US PhRMA from 2005 to 2006 and chaired the Biostatistics and Data Management Technical Group (BDMTG) that leads biometric interactions between the US pharmaceutical industry and the FDA for many initiatives such as the Critical Path Initiative from FDA.

About the Speakers *continued*

William Wang, PhD

Dr. William (Bill) Wang is the head of the China operations for the Department of Biostatistics and Research Decision Sciences (BARDS) in the Merck Research Laboratories (MRL). This department provides critical statistical support in the design and execution of Merck's clinical development programs.

Dr. Wang has over 15 years of experience in the pharmaceutical industry in the United States, with expertise in statistical design/analysis, scientific programming and clinical data management. He has worked for Fox Chase Cancer Center, Astra Merck, Covance, and Merck & Co., Inc. During his ten-year tenure at Merck, he has led the statistical supports for major regulatory filings of drug/vaccine products, which won him Merck's key innovator award (2005). He has been active in statistical researches, with more than 40 statistical publications/presentations. He was assigned to establish the BARDS China operations in late 2007.

Over the last five years, Bill has served on the steering/organizing committees for the FDA/Industry workshop and the Deming Applied Statistics Conference. He co-organized the 1st International Symposium on Biopharmaceutical Statistics (ISBS), July 2008 in Shanghai. Recently, he co-founded the Shanghai Biostatistics Forum (SBF) with a mission of promoting biometrics professionals in China as an international talent force (http://stat.smmu.edu.cn/sbf/main.htm). He is also a working member of the PhRMA's Adaptive Design Task Force.

Bill has a PhD in Statistics and an MS degree in Mathematics and Computer Sciences from Temple University, as well as an MS in Computational Mathematics from Jilin University.

Weiying Yuan, PhD

Dr. Yuan is currently Site Head of Biostatistics and Clinical Informatics in Asia, Johnson and Johnson Pharmaceutical Research and Development (J&J PRD). She has been training and managing a group of biostatisticians and SAS programmers in Shanghai to provide biostatistical support to the J&J global clinical trial projects. She has gained broad experiences in global new drug development during her sixteen years working in the pharmaceutical companies. In her previous role as Senior Director, Clinical Biostatistics in Internal Medicine (IM), Weiying managed projects and staff members who were responsible for providing statistical support in the urologic, metabolism, and reproductive therapeutic areas in IM. Prior to IM, as a Global Statistical Leader, she led teams of biostatisticians and SAS programmers working on various successful worldwide filings and approvals of new drugs as well as new indications of marketed drugs in the antipsychotic and neurological product teams in the CNS area.

Prior to J&J, during her six-year tenure at Merck, she had been a major contributor to the successful approval of Worldwide Medical Applications (WMAs) and New Drug Applications (NDAs) for new drugs on osteoporosis, analgesics, and arthritics.

Dr. Yuan received her PhD and MS degrees in Biostatistics at the University of Michigan and her BA in English Literature at Beijing Normal University. Her research interests include multivariate analysis, longitudinal and missing data analysis, and design and analysis of all phases of clinical trials. She has many professional publications in biostatistics and clinical trial applications and has given lectures at the Fudan and Jiaotong Universities as well as to the CDE/SFDA staff.

About DIA

DIA is a professional association of more than 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance, or marketing of pharmaceuticals or related products.

DIA is committed to the broad dissemination of information among its members, with continuously improved professional practice as the goal. DIA serves its members in a neutral, global environment that operates independent of the influence of any one organization or authority.

DIA operates as a financially independent nonprofit organization that funds itself from meeting and membership fees. The voluntary efforts of DIA members and speakers allow DIA to provide programs and publications to members at a reasonable, competitive cost.

DIA Mission

DIA is a nonprofit, multidisciplinary, neutral forum for sharing information that optimizes the process of drug development and lifecycle-management by providing:

- Global and regional forums for the exchange of information, education, and training;
- Extensive multidisciplinary networking opportunities;
- Rewarding volunteer leadership experiences; and
- High-quality professional development opportunities.

DIA Vision

DIA is the universally respected forum for quality information exchange leading to better medicines that enhance health and well-being.

DIA is pleased to open an office in Beijing, offering the services of conferences, training, and membership to this new, exciting region.

Please monitor DIA's website often for the latest developments of DIA in China.

www.diahome.org

The First DIA Training Workshop in China:
Understanding the Statistical Thinking in Clinical Research for Drug Development

Meeting I.D. # 09975 – May 11-12, 2009 – Hotel Equatorial Shanghai, SHANGHAI, CHINA

TRAVEL AND HOTEL

A group rate has been made available to registrants at the Hotel Equatorial Shanghai: Standard Room (RMB750/night incl. breakfast). When making your reservation please indicate that you are participating in the DIA China Workshop. Please note that registrants are kindly requested to make their own transportation and accommodation arrangements; DIA is not responsible for transportation, accommodation or other costs incurred by registrants.

Please contact the Hotel Equatorial Shanghai and mention the DIA meeting.

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65 Yanan Road West, Shanghai 200040, People's Republic of China
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Web: www.equatorial.com/sha/

▶ **DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for any airfare, hotel or other costs incurred by registrants.**

MEETING CONTACT INFORMATION

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North Road East 3rd Ring, ChaoYang District, Beijing, 100027, China
Tel: +86-10-5923-1109; Fax: +86-10-5923-1090; www.diahome.org.

CANCELLATION POLICY: On or before MAY 4, 2009

Cancellations must be in writing and be received by May 4, 2009. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. If the event is cancelled, the organizers are not responsible for any airfare, hotel or other costs incurred by registrants.

Upon cancellation, the administrative fee that will be withheld from refund amount is:

Full meeting cancellation:
Member/Nonmember = **RMB 1368**
Government/Academia/Nonprofit Member/Nonmember = **RMB 684**

Workshop Registration Fees

Registration fee includes refreshment breaks, luncheons, and meeting materials, and will be accepted by mail, fax, or eMail.

MEMBER EARLY-BIRD OPPORTUNITY *Available on nondiscount member fee only*	On or before April 13, 2009	On or after April 14, 2009
Member	RMB 2016 ❑	RMB 2240 ❑
Nonmember *(Workshop only)*		RMB 2800 ❑
Become a DIA member now for RMB 880, and qualify to register for this meeting at the applicable member rate.		MEMBERSHIP RMB 880 ❑

To qualify for the early-bird member discount rate, registration form and accompanying payment must be received by the date above. Does not apply to government/academia/nonprofit members.

Discount Fees	MEMBER	NONMEMBER*
Government (Full-time)	RMB 784 ❑	RMB 980 ❑
Charitable Nonprofit/Academia (Full-time)	RMB 1456 ❑	RMB 1820 ❑

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eMail your information to the attention of Ms. Stephanie Liu to dia@diachina.org or fax to +86-10-5923-1090. After receipt of payment, the invoice and a member card will be mailed to you.

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DRUG INFORMATION ASSOCIATION

药物信息协会（DIA）培训讲习课程

理解药物临床研究中的统计学思维

2009年5月11–12日 | 中国　上海国际贵都大饭店

主席

谭凌实 博士
辉瑞(中国)研究开发有限公司总经理

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内容概览

本次为期两天的培训讲习班是专为那些由于学习或工作需要经常接触统计学的从事药物研发的专业人员设计的有深度的、切合实际的、基础到中等程度的课程。本课程将简短复习有关基础统计学概念，介绍统计学原理要素，强调统计学在药物临床研究过程中的实际应用，并安排互动讨论环节，帮助参会者正确理解药物临床试验设计和分析中的统计学思维。本次培训课程将着重于肿瘤药物临床试验、非劣效性及等效性设计。

参会人员

如果您从事的工作与临床研发相关，并且在工作中必须了解和运用统计学概念，那么本次课程将使您有所斩获，不虚此行。

- 临床研究运作
- 临床科学
- 法规事务
- 项目管理
- 数据管理和生物统计

学习目的

在讲习班结束时，与会者应能够：

- 理解在课程中讨论的基本统计学概念及其实际应用
- 认识在肿瘤临床试验的设计与分析中关键的统计学问题
- 理解如何确立非劣效性或等效性
- 与统计专业人员密切合作

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周一 2009年5月11日

7:30–8:30 注册

8:30–8:40 主席欢迎致辞
谭凌实 博士

8:40–10:40 第一节

生物统计学实论
沈志华 博士

本节将简要复习基础统计学概念和方法，尤其着重于讲解与此次课程主题相关的内容。

- 统计学是循证医学的基础
- 第一类错误与第二类错误
- 样本量估计
- 前瞻性分析与回顾性分析
- 多样性与中期分析
- 生存分析

10:40–11:00 茶歇

11:00–12:30 第二节

肿瘤药物临床试验的统计学方法
曲鹏 博士

抗肿瘤药是新药临床研发最活跃的领域之一。肿瘤药物临床试验的设计、执行和分析给临床试验参与者和其他从事药物开发的专业人员带来了许多独特的特点和挑战。这一节将通过讲解和实例分析，对肿瘤药物临床试验中普遍运用的统计分析方法和结果作一全面的阐述。

- 研究设计
- 疗效评价终点
- 临床数据汇总
- 统计推论
- 治疗间比较

12:30–13:45 午餐

13:45–15:30 第二节（续）

肿瘤药物临床试验的统计学方法
曲鹏 博士

15:30–16:00 茶歇

16:00–17:00 第二节（续）

肿瘤药物临床试验的统计学方法
实例分析：抗肿瘤药物的开发（第一部分）
黄克欧博士

17:30–19:00 交流招待会

周二 2009年5月12日

7:30–8:30 注册

8:30–10:00 第三节

非劣效性和等效性试验
黄克欧 博士
王武保 博士
袁维颖 博士

越来越多的临床试验使用阳性对照来研究新的受试药的疗效和安全性。在这一节中，我们将着重于那些以证明新受试药不劣于阳性对照药为主要研究目的阳性对照试验。本节讨论的重点是为保证该研究目的顺利完成而必须了解和掌握的基本概念和实践，以及探讨三个实际案例。

设计、分析和推论：概念与实践

- ICH E10指南—对照组的选择
- 优效性试验和非劣效性/等效性试验
- 检验灵敏度与恒定性假设
- 非劣效性边际与对照效果保留分数
- 样本量与检验效能
- 非劣效性推论
- 评价目标/转换目标
- 规章及运作上的挑战
- 其他有用的备选方法

10:00–10:30 茶歇

10:30–12:00 第三节（续）

非劣效性和等效性试验

12:00–13:15 午餐

13:15–15:30 第三节（续）

非劣效性和等效性试验/非劣效性试验实例分析

- 风湿性关节炎药物开发中胃肠道安全性的评价
- 抗糖尿病药物的开发
- 抗肿瘤药物的开发（第二部分）

黄克欧 博士
王武保 博士
袁维颖 博士

15:30–16:00 茶歇

16:00–17:30 第四节

小组讨论与问答
所有讲者

17:30 主席总结致辞
谭凌实 博士

讲者简介

谭凌实 博士

谭凌实博士是辉瑞（中国）研究开发有限公司的创始人，总经理。该研发中心于2005年在上海成立。此前自2001年起，谭博士就一直担任辉瑞总公司日本，亚洲，非洲，中东和拉丁美洲的生物统计数据管理部的总负责人。在此期间，他成功地建立并管理了多个生物统计数据中心，包括2002 年在悉尼成立的亚洲生物统计数据中心和2004 年在纽约成立的拉丁美洲生物统计数据中心。谭博士于1996 年加入在纽约的辉瑞总公司，在此以前相继在匹兹堡儿童医院和新泽西的先灵葆雅研究所工作，并从1999 年就开始参与了一些中国的项目。他在行内已有16年的工作经验。谭博士的文章和报告涵盖统计学理论和临床研究领域。谭博士毕业于美国匹兹堡大学，拥有应用数学硕士和生物统计学博士双学位。谭博士分别被北京大学国际药物工程管理研究生项目和复旦大学药学院聘为咨询委员会顾问。

黄克欧 博士

黄克欧博士（宾州大学Wharton学院统计学博士）目前任美国Irving Consulting Group（ICG）统计咨询顾问公司总裁，新泽西医科和牙科大学特约教授，中国第二军医大学医学卫生统计客座教授。此前，黄博士曾任Harvard Clinical Research Institute（HCRI）哈佛临床研究院资深副总裁，Hoechst Marion Roussel公司全球生物统计副总裁兼总监，默克制药公司临床生物统计和研发数据系统总监。他也曾任ICH E10专家工作组制药专家副组长。

黄博士拥有近三十年的全球药物开发经验，特别是制药和生物技术公司中从事新药与疫苗开发临床试验设计与分析。他拥有丰富的亲历经验并取得了多项新药/新生物制品申请（NDAs/BLAs）和欧盟注册（MAAs）的成功。他在全球新药开发的高端生物统计咨询方面极具专长。他在临床试验，包括探索性试验、验证性试验、适应性和阳性对照试验的设计与分析等的统计方法论上提供咨询业务。他为客户提供统计问题的解决方案。此外，他还是独立的数据监测委员会的主席/成员。

黄博士在美国宾夕法尼亚大学沃顿商学院获得统计博士学位。他曾在新泽西医科和牙科大学及罗格斯大学教授生物统计研究生课程。此外，他还在第二军医大学、复旦大学和上海交通大学教授课程。黄博士发表过众多的关于统计学和临床试验应用的专业论文和报告，并举办专题讲座，其中包括DIA、ICSA以及SFDA的课程等。

曲鹏 博士

曲鹏博士，辉瑞（中国）研究开发有限公司统计部总监，他和他领导的统计团队为辉瑞全球和区域性的药物开发临床试验提供统计上的支持。

在加入辉瑞之前，曲博士先后在Hoechst Marion Roussel，R.W. Johnson Pharmaceutical Research Institute和Forest Laboratories，Inc担任不同职位。从最早的研究统计员到Forest Laboratories，Inc生物统计的高级总监，在他十几年的职业生涯中，随着工作职责的不断扩大，他担任了不同职位。曲博士带领着他的统计团队在一些重要的治疗领域，包括心血管，胃肠道、疼痛和呼吸系统疾病等，为临床开发和法规提交提供支持。

曲博士擅长临床统计，例如纵向追踪数据和缺失数据的分析、多重比较进程、组群序贯分析和生存分析等。他曾发表许多统计文章并在众多统计期刊中作为第一作者发表论文，如《Biometrics》《Statistica Sinica》，《Statistics and Probability Letters》、《Communications in Statistics》、《Controlled Clinical Trials》等。

曲鹏博士毕业于中国华东师范大学数学系，之后获得美国威斯康辛大学麦迪逊分校统计学博士学位。

沈志华 博士

沈志华博士在2007年加盟罗氏药品开发中国中心担任生物统计和临床研究管理总监。之前他是美国施贵宝（Bristol–Myers Squibb）公司研发 、全球生物统计部门执行总监，一直领导着由统计学家、程序设计师和数据管理约80余人员组成的团队完成既定的使命，即在新药探索、药物相关基因，临床药理学和临床药代动力学各方面，使科学家和统计学家在数据和统计上的密切合作更加一体化，加速早期药物的研发。沈博士也曾是施贵宝公司临床科学委员会和临床最优程序委员会的成员，负责临床方案的评审和监督临床研究和活动进程，监督施贵宝亚太地区国家生物统计和数据分析有成效的发展。

沈博士于1989年进入制药行业，1993年以前在惠氏（Wyeth）全球药品开发研究中心担任统计研究专家；其后作为主管加盟了默沙东（Merck & Co.）公司的生物统计研究组。1996年加盟施贵宝全球药品开发研究中心，并从那时起，不断的得到晋升至执行总监。沈博士在台湾的中原大学和美国德克萨斯州的Lamar大学获得化工专业的学士和硕士学位后，在美国Temple大学获得统计学博士学位。

此外，沈志华博士还积极参与专业领域的各项活动。他是美国统计协会的会员及入选为2003年的院士（Fellow），并被推选为全球华人统计协会主席。同时，他还在2005至2006年间担任美国药物研究及生产协会（PhRMA）生物统计和数据管理指导委员会的主席，负责领导药界与美国食品及药品管理局（FDA）在专业上的交流和沟通。

讲者简介

王武保 博士

王武保博士是美国默沙东公司默克研究所(MRL)生物统计和研究决策科学部(BARDS)中国运营部总监，为默沙东临床发展项目的设计与执行提供临床统计支持。

王博士在美国的制药行业工作了15年，擅长于统计设计/分析、科学程序和临床数据管理。他曾先后在Fox Chase癌症中心、Astra Merck、Covance 以及默沙东任职。在默沙东任职的十年间，由于在药物/疫苗产品的主要法规文档整理汇集上领导和提供了出色的统计支持，他于2005年赢得了默沙东关键创新奖。2007年，他被委任在中国创立生物统计和研究决策科学部(BARDS)中国运营部。此外，王博士还活跃于统计研究领域，曾发表了40多篇统计论文和报告。

在过去的5年中，王博士还曾高度参与/组织了FDA/行业的短期培训和“Deming 应用统计大会”。2008年7月，他联合组织了在上海举办的第一届国际生物制药统计研讨会。最近，为了推动中国生物统计专业人员作为国际人才队伍中的重要部分，他还联合创办了上海生物统计论坛(SBF)。此外，王博士还是“制药应用设计特别工作组”(PHRMA's Adaptive Design Task Force)的成员。

王博士毕业于吉林大学计算数学系并获得硕士学位，之后获得美国天普大学数学和计算机硕士学位，以及天普大学统计学博士学位。

袁维颖 博士

袁维颖博士现任强生药物研发亚洲生物统计和临床信息资深总监。她在上海负责对生物统计和SAS程序职员进行培训和管理，并为强生全球临床试验各方项目提供支持。16年制药行业生涯令袁博士积累了非常丰富的经验，特别是在全球新药开发方面。袁博士曾在内科 (IM)临床生物统计任资深总监，进行项目和人员管理，以及对泌尿、代谢和生殖疾病治疗提供统计支持。此前，作为全球生物统计的领导，她带领她的团队，包括生物统计员和SAS程序员，在中枢神经系统领域中抗精神病药物、神经性药物的全球文档整理汇集与新药审批及药物新适应症等工作上取得了成就。加入强生前，袁维颖博士在默克制药公司工作了六年，为骨质疏松症、镇痛药和关节炎等药物的全球药物注册 (WMAs) 和新药申请 (NDA)作出了突出贡献。

袁维颖博士拥有北京师范大学英语文学专业学士学位，并在美国密歇根大学获得生物统计硕士和博士学位。她的研究成果包括多元分析、纵向追踪数据和缺失数据的分析、临床试验各阶段的设计与分析。她在生物统计和临床试验应用方面发表了许多文章，并在复旦大学、上海交通大学、中国国家食品药品监督管理局和药品审评中心等机构讲授课程。

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