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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

LING SU, PhD
Vice President, Clinical Research & Development
Asia Pacific Research Organization
Wyeth Pharmaceutical Co., Ltd., China

CLAIRE TAN, MS, MBA
Director, Biostatistics
Quintiles Medical Development (Shanghai) Co., Ltd., China

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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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

Ms. Stephanie Liu, Drug Information Association, China Office:
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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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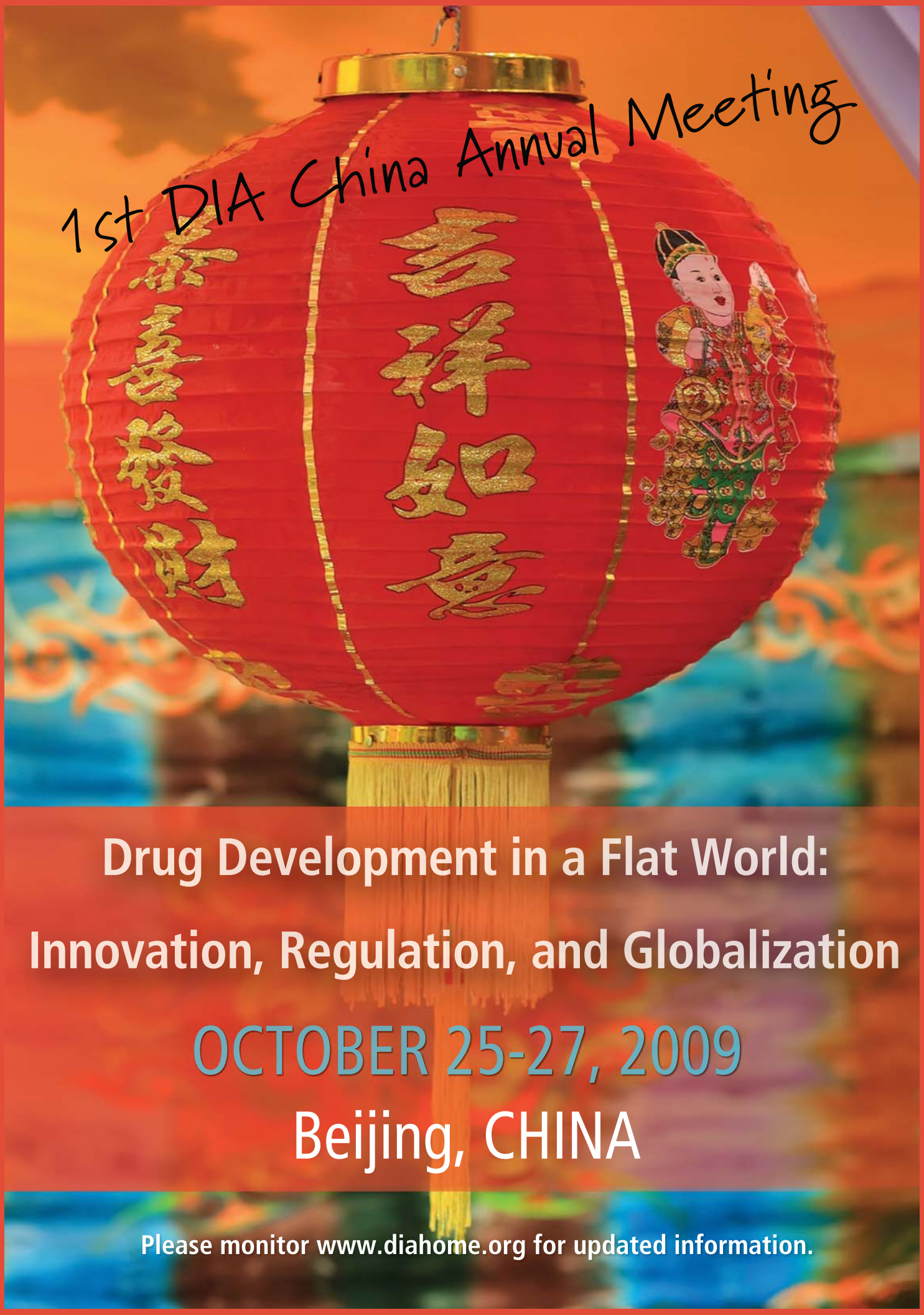

Drug Development in a Flat World: Innovation, Regulation, and Globalization

OCTOBER 25-27, 2009

Beijing, CHINA

Please monitor www.diahome.org for updated information.