2nd DIA China Annual Meeting

Priming China for Drug Innovation and Development: From Strategy to Execution

Workshops: May 16, 2010

Conference: May 17-19, 2010

PROGRAM CO-CHAIRPERSONS

Frank JIANG, MD, PhD
Vice President, Global R&D and Head, China R&D
sanofi-aventis, China

ZHAO Yajun
Director-General, China Center for Pharmaceutical International Exchange, SFDA, China

PROGRAM COMMITTEE

James CAI, MD
Vice President, Clinical Development
aTyr Pharma, China

Lili CAO
Division Director
China Center for Pharmaceutical International Exchange of the SFDA, China

Paul DAI, MD
Director, Clinical Development
Beijing Novartis Pharma Co., Ltd., China

Kewen JIN, PhD
General Manager
Charles River Preclinical Services, China

LI Haiyan, MD
Vice Director, Peking University Clinical Research Institute
Director, Drug Clinical Trial Center
Peking University Third Hospital, China

LI Ning, MD, PhD
Senior Group Regulatory and Medical Policy Director
sanofi-aventis China

Joanne LIU, MS
Manager, Asia Pacific Data Management Center
Merck Research Laboratories, Merck & Co., Inc, China

Ling SU, PhD
Vice President
Asia Pacific Research Organization
Pfizer, China

Lily SUN, MD
Head of Medical
Pfizer Pharmaceutical Ltd., China

Peng WANG, PhD
Chief Scientific Officer
Simcere Pharmaceutical Group, China

Spring WANG, MD
Director of Clinical Research & Development
Xi'an Janssen Pharmaceutical Ltd., China

William WANG, PhD
Head of Asia Pacific Hub, Department of Biostatistics and Research Decision Sciences, Merck Research Laboratories
Merck & Co., Inc, China

China's drug innovation and development are moving ahead rapidly. A local, as well as global, perspective will help all players involved to exchange critical information for research and strategic positioning in an increasingly complex regulatory landscape.

This second DIA China Annual Meeting will serve as an international, neutral forum for attendees to collectively discuss how China can play a leadership role in drug development. Speakers from major regulatory agencies, industry, and academia will present and lead the panels and sessions.

This multidisciplinary meeting will benefit all professionals from regulatory agencies and institutions, the biopharmaceutical industry, investigational sites, contract research organizations, and academia. Together we can better understand how to reach the next stage for our profession as well as deliver benefits for human health and well-being globally.

KEY SESSIONS AND TOPICS

General Session Topics

- Regulatory Affairs
- Clinical Research
- Pharmacovigilance
- Clinical Data Management and Statistics
- Non-clinical Safety Assessment
- CMC/GMP
- R&D and Biotechnology

WHO SHOULD ATTEND

This program will benefit individuals involved in:

- Regulatory affairs
- Clinical research
- Drug R&D strategies
- Quality assurance and quality control
- Drug safety and pharmacovigilance
- Strategic sourcing/planning
- Bioinformatics
- Biostatistics

Simultaneous translation will be available on May 17-19.

CONTACT INFORMATION

Conference: For general inquiries and registration, contact Ms. Stephanie Liu at dia@diachina.org

Exhibits: Contact Ms. Tina Peng at dia@diachina.org

Co-sponsored by

China Center for Pharmaceutical International Exchange of the SFDA

www.diahome.org

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Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

PRE-CONFERENCE WORKSHOPS |SUNDAY, MAY 16

8:30 – 12:30 WORKSHOP 1

Enhance Drug Safety through Prospective Planning, Timely Evaluation, and Effective Reporting

With an increasing public awareness of safety issues relating to medical products, both regulatory agencies and pharmaceutical companies are making more efforts to ensure drug safety throughout the entire product life cycle. This workshop aims at presenting comprehensive approaches to manage safety issues during clinical development, from prospective planning, timely safety monitoring and review to effective reporting. The workshop will use real life examples to demonstrate how this 3-way approach can enhance drug safety. The workshop will contain the following specific topics:

- Safety trial design and analysis: safety endpoints and definitive safety trial, safety analysis plan, meta-analysis
- Early spotting safety signals using an effective tool – Data Surveillance Plan (DSP)
- Role of Ethical Committee and DMC
- Effective safety reporting

Who Should Attend

This workshop will benefit those who work in relevant areas in drug development and medical marketing in the industry and who are practicing physicians treating patients and conducting clinical trials in healthcare institutions, including, but not limited to:

- Clinical trial investigators
- Clinical research and development
- Clinical research operations
- Drug safety and pharmacovigilance
- Regulatory affairs
- Biostatistics and data management
- Medical writing
- Medical practicing

Learning Objectives

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

- Well recognize the importance of effective safety monitoring and reporting in drug development
- Obtain a full picture of leading approaches to manage safety concerns in clinical development
- Understand Regulatory perspective and directions

SPEAKERS

Frank JIANG, MD, PhD
Vice President, Global R&D and Head China R&D
sanofi-aventis, China

CHEN Xun, PhD
Head of China Clinical Sciences & Operations
sanofi-aventis, China

James HUNG, PhD
Director, Division of Biometrics I, Office of Biostatistics, Center for Drug Evaluation and Research (CDER), FDA, USA

Robert MAKUCH, PhD
Professor of Biostatistics and Director, Regulatory Affairs Program, Yale University School of Medicine, USA

PRE-CONFERENCE WORKSHOPS |SUNDAY, MAY 16

8:30 – 12:30 WORKSHOP 2

Critical Appraisal of the Medical Literature

About the Workshop

In today's fast changing world, scientists, researchers, physicians and students are faced with an overwhelming number of medical research articles in their professional work. How can we efficiently read the medical literature and identify the valid and valuable evidence from the mountain of information? This workshop gives an anatomy of the essentials of a medical research article and introduces the commonly recognized reporting practice. Based on a brief review of research study design and statistical methodology, the workshop will use real examples to illustrate how to efficiently, thoughtfully, and critically appraise the medical literature. In an interactive setting, papers of randomized clinical trials, vaccine efficacy trials and pharmacoepidemiologic study will be discussed. Pre-workshop reading and preparation are required.

Who Should Attend

This workshop will benefit those who work in relevant areas in drug development and medical marketing in the industry and who are practicing physicians treating patients and conducting clinical trials in healthcare institutions. The workshop will also be helpful to students, researchers, and other health professionals who need to understand medical literature in their work or study, including those involved in:

- Clinical research and development
- Clinical trial investigation
- Medical practice
- Medical information and communication
- Medical writing
- Regulatory affairs
- Clinical research operations
- Drug safety and pharmacoepidemiology
- Biostatistics

Learning Objectives

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

- Describe the essential components of medical research articles and good reporting practice
- Discuss basic health research design and statistical methodology
- Better understand a study's design, conduct, analysis and interpretation, and critically assess the validity of its results, identify its flaws, limitations and the implications
- Distinguish solid medical literature to poor medical literature

Speakers

Ling SU, PhD
Vice President
Asia Pacific Research Organization
Pfizer, China

William WANG, PhD
Head of Asia Pacific Hub
Department of Biostatistics and Research Decision Sciences
Merck Research Laboratories, Merck & Co., Inc., China

13:30 – 17:30 WORKSHOP 3

Clinical Trial Monitoring, Auditing, and Inspection Workshop — FDA, SFDA, and Industry Perspective

About the Workshop

In recent years, more and more global clinical trials have moved from the West to the East, especially to China. The regulatory agencies worldwide are paying more and more attention to the quality of clinical trials. As a result, a large number of clinical sites were selected and inspected by FDA or SFDA. This workshop will help you understand the importance of clinical trial monitoring and auditing and learn how audits and inspections are conducted, as well as regulatory agencies' expectations. You will learn FDA foreign country inspections procedures, GCP requirements, site selection criteria, and common issues during inspection and how to prepare for FDA or SFDA inspections.

Who Should Attend

This workshop will benefit those who are involved in:

- Clinical research operations
- Clinical trial investigators
- Clinical study coordinators
- Clinical reseach unit managers
- Quality assurance and quality control
- Regulatory affairs
- Drug safety and compliance
- Data management

Learning Objectives

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

- Learn audit and inspection techniques, practices and common findings from a former FDA inspector to enable you to be better prepared when the time comes for you to be inspected
- Understand how seemingly minor findings can lead to serious problems for the investigator, sponsor, and CRO
- Learn how to manage issues identified during audits and inspections

Speakers

Byungja MARCIANTE
Assistant Director/Investigator,
US FDA China Office

Speaker invited from SFDA

Blake R. JENSEN, BS
Senior Director, Quality Assurance
INC Research, Inc

LI Ning, MD, PhD
Sr. Group Director Regulatory & Medical Policy China
sanofi-aventis China

CONFERENCE DAY 1 | **MONDAY, MAY 17**

8:30 – 9:30 PLENARY SESSION

WELCOME

Richard O. Day, AM, MB, BS, MD, FRACP
President-Elect, Drug Information Association
Professor of Clinical Pharmacology, St. Vincent's Hospital, Australia
Paul Pomerantz
Worldwide Executive Director
Drug Information Association. USA

OPENING REMARKS

Frank Jiang, MD, PhD
Vice President, Global R&D and Head, China R&D
sanofi-aventis, China
ZHAO Yajun
Director-General, China Center for Pharmaceutical International Exchange, SFDA, China

KEYNOTE ADDRESS:

Speaker invited

9:30 – 10:00 BREAK

10:00 – 12:00 PLENARY SESSION

Overview of SFDA's Drug Regulatory Strategies and Priorities
Speaker invited

Healthcare Reform and Innovation
Speaker invited

Enhance R&D Value Through Partnership
Speaker invited

R&D Innovation: A New Era for China's Pharma Industry
Speaker invited

12:00 – 13:30 LUNCH

13:30 – 17:30 PARALLEL TRACKS – SESSION 1 **15:00 – 15:30** REFRESHMENT BREAK

Session 0101

Best Regulatory and Development Practices from the USFDA

Chairperson
LI Zili, MD, MPH
Co-chair, FDA Alumni Association International Network (FDAAAIN); Director, Merck & Co., China

Best Regulatory and Development Practices in Oncology
Robert DELAP, MD
Former ODE V Director, CDER/USFDA; Vice President, Celgene Corporation; FDA Alumni Association (FDAAA); USA

Best Regulatory and Development Practices in Anti-Infectives
Mark J. GOLDBERGER, MD, MPH
Former ODE VI Director
CDER/USFDA; Vice President
Abbott FDAAA; Abbott, USA

Best Regulatory and Development Practices: Themes from US FDA
Florence HOUN, MD, MPH
Former ODE III Director;
Vice President;
CDER/USFDA; Celgene FDAAA, USA

Best Regulatory and Development Practices in Pulmonary/Anti-Inflammation
Robert J. MEYER, MD
Former ODE II Director;
Vice President
CDER/USFDA; Merck & Co. FDAAA; Merck & Co., USA

Session 0102

Capacity Development and Management of Clinical Trial Sites

Chairperson Invited

Training Of Clinical Research Professionals In An Academic Setting – US Perspective
Stephen A. SONSTEIN
Professor and Director
Clinical Research Administration
East Michigan University, USA

Model of Clinical Research Nurses Training in China
CAO Ye
Research Associate/Attending Physician
Clinical Trials Cener, Sun Yat-sen University Cancer Center, China

Investigator Network
Speaker Invited
Korean Network of Enterprises of Clinical Trials (KoNECT), Korea

Discussion on the Current Management Mode of Chinese Drug Research Organizations
HU Jingqing
Director of Center for Clinical Research, Director of Office of State Institution for Drug Clinical Research, Guang' anmen Hospital, Academy of Chinese Medical Science. Guang'anmen Hospital, Academy of Chinese Medical Science, China

Session 0103

Updates on ICH Quality Guidelines and Implications

Chairperson
Chi-wan CHEN, PhD
Planning Committee Member; Executive Director
FDA Alumni Association International Network; Pfizer, Inc., USA

Introduction: ICH Q8/9/10 – A New Paradigm
Chi-wan CHEN, PhD
Planning Committee Member; Executive Director, FDA Alumni Association International Network; Pfizer, Inc., USA

ICH Q8/Q8R Pharmaceutical Development
Moheb NASR, PhD
Director, Office of New Drug Quality Assessment; CDER, FDA,USA

ICH Q9 Quality Risk Management
Rick FRIEDMAN (TBC)
Deputy Director
Office of Compliance, Division of Product Manufacturing and Quality
CDER, FDA, USA

ICH Q10 Pharmaceutical Quality System
Joseph FAMULARE
Senior Director, Quality and Compliation, Genetech, USA

Implications of ICH Q8/9/10 in China
Speaker invited
Center for Drug Evaluation, SFDA, China

Session 0104

Clinical Data Standards: Have You Got Your Data Quality Measurement In Place?

Chairperson
Hanming H. TU, MS, MCRP
Director
Octagon Research Solutions, USA

Clinical DQI: Measurement and Factors Impacting Clinical Data Quality
Hanming H. TU, MS, MCRP
Director
Octagon Research Solutions, USA

Improving Data Quality for Submissions by Implementing Standards
Paul S. CHUNG, MS, MBA
Executive Vice President
Image Solutions, Inc., USA

Globalizing Data Standards Using Existing CDISC/HL7 Models and Guidance
Shawn WANG, MBA
MedXview Inc, USA

The Data Quality Driven Innovation in CRO Industry (Domestic eRDDM)
Xueyou Danny HU, PhD
General Manager
Real Data Medical Research Inc., China

Cost-effective, Metadata-driven Technology for Implementing CDISC SDTM
Mike TODD, MA, MS
President
Nth Analytics, USA

18:00 – 20:00 NETWORKING RECEPTION

CONFERENCE DAY 2 | **TUESDAY, MAY 18**

8:30 – 12:00 PARALLEL TRACKS – SESSION 2 9:30 – 10:00 REFRESHMENT BREAK

Session 0201

Responding to the Evolving Regulatory Environment

CHAIRPERSON

Wen CHANG, PhD
Head of Regulatory Intelligence and Advocacy, Asia-Pacific Region, Global Drug Regulatory, Beijing Novartis Pharma Ltd. China

Update from the Center for Drug Evaluation
Speaker invited
Center for Drug Evaluation, SFDA, China

Update on the APEC Harmonization Initiative
Speaker invited
Regulatory Harmonization Steering Committee, LISF, APEC

Progress report MHLW's Five-year Plan and PMDA Initiatives
Speaker invited
Pharmaceuticals and Medical Devices Agency (PMDA), Japan

Additional speaker and panelist invited

Session 0202

Ensuring Safety of Participants in Exploratory Development Studies

CHAIRPERSON

Paul de KONING, MD, PhD, FFPM
Vice President Exploratory Development, Astellas Pharma Global Development, Netherlands

First in Human: Safety First
Paul de KONING, MD, PhD, FFPM
Vice President Exploratory Development, Astellas Pharma Global Development, Netherlands

First in Human: Healthy Volunteers or Patients?
Ronald SMULDERS, MD, PhD
Medical Director, Exploratory Development, Astellas Pharma Global Development, Netherlands

Use of Modeling and Simulation in Exploratory Development
Cornelia WEBER, PhD
Senior Clinical Pharmacologist
Clinical Pharmacology
Shanghai Roche Pharmaceuticals Ltd, China

Safety Biomarkers in Exploratory Development
Elizabeth ALLEN, PhD
Deputy Unit Head and Director of Scientific Affairs Quintiles, UK

Session 0203

Safety Signal Detection: A Needle in a Haystack? Sharing Experiences from Regulatory and Industry Perspectives

CHAIRPERSON

Anna Zhao-WONG, MD, PhD
Deputy Director, MedDRA Maintenance and Support Services Organization, USA

What are the Positive and Challenging Aspects of Using MedDRA to Identify Potential Safety Signals?
Anna Zhao-WONG, MD, PhD
Deputy Director, MedDRA Maintenance and Support Services Organization, USA

Signal Detection from a Regulatory Perspective – Clinical Trial
C. George ROCHESTER, RN, MA, PhD, RAC
Associate Director for Safety Assessment
Office of Biostatistics
US FDA

Signal Detection from a Regulatory Perspective – Postmarketing Surveillance
Mick FOY
Group Manager
MHRA, UK

Signal Detection from a Company Perspective
Speaker invited

Session 0204

Key Statistics Issues in Modern Clinical Trial Designs

CO-CHAIRPERSONS

William WANG, PhD
Head of Asia Pacific Hub Department of Biostatistics and Research Decision Sciences, Merck Research Laboratories, Merck & Co., Inc, China

Ning LI, MD, PhD
Senior Group Regulatory and Medical Policy Director
sanofi-aventis China

Statistical Consideration in Adaptive and Noninferiority Guidance
H.M. James HUNG, PhD
Director, Division of Biometrics I, Office of Biostatistics
Center for Drug Evaluation and Research (CDER), FDA, USA

Margin Selection and Result Interpretation in Non-Inferiority Trials
Gang CHEN, PhD
Director of Biostatistics
Group Leader, Oncology, Johnson & Johnson, China

Statistical Consideration in Multi-Regional Clinical Development
Xun CHEN, PhD
Biostatistics and Programming Site Head, China R&D Center
sanofi-aventis, China

PANELIST

Frank SHEN, PhD
Asia Pacific Head of GPD Biometrics
Roche, China

CONFERENCE DAY 2 | **TUESDAY, MAY 18**

13:30 – 17:30 PARALLEL TRACKS – SESSION 3 15:00 – 15:30 REFRESHMENT BREAK

Session 0301

Global Clinical Development and Best Regulatory Meeting Practices in US, EU, Japan, and China

CHAIRPERSON

Alberto GRIGNOLO, PhD
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting, USA

How to Conduct Effective Clinical Development Meetings with the US FDA
Alberto GRIGNOLO, PhD
Corporate Vice President, Global Strategy and Services, PAREXEL Consulting, USA

The EU Scientific Advice Process: Roadmap for Clinical Development Success
Michael ROZYCKI, PhD
Vice President and Head, Global Regulatory Affairs Asia, Bayer HealthCare Company Ltd., China

Effective Clinical Trial Consultations with the Japanese PMDA
SATOSHI Koike, PhD
Representative DirectorAmgen Development K.K.,Japan
PMDA Speaker Invited

Effective Interactions Between Industry and CDE in China on Clinical Development
Speaker Invited
Center for Drug Evaluation, SFDA, China

Additional speaker and panelist invited

Session 0302

Efficient Sponsor-Investigator-CRO-Vendor Collaboration to Ensure Quality of Clinical Trials

CO-CHAIRPERSONS

JIAO Qingan, MD
Director, Clinical Research Unit, R&D China, sanofi-aventis, China

Rachel YANG, MD, PhD
Director, Product Strategy, Health Sciences Global Business Unit,Oracle Corporation, China

How to Improve Efficiency and Quality of Clinical Studies in China: The Sponsor's Perspective
Paul DAI, MD
Director, Clinical Development
Beijing Novartis Pharma Co., Ltd.
China

Co-source/In-sourcing Model: A Solution for the Management of Resources
XU Ning, MD, MBA
Senior Director
Head of CDS, China
Covance Pharmaceutical Research and Development (Beijing) Co., Ltd., China

Leading Large Global Cardiovascular Studies in China: The Role of the National Coordinator
Zhu Jun, PhD
Professor
Beijing Fuwai Hospital, China

Improve Trial Efficiency and Improve Trial Quality with Clinical Trial Management System
Rachel YANG, MD, PhD
Director, Product Strategy, Health Sciences Global Business Unit
Oracle Corporation, China

Panelist:
LI Haiyan, MD
Vice Director, Peking University Clinical Research Institute; Director, Drug Clinical Trial Center, Peking University Third Hospital, China

Session 0303

Pharmacovigilance During Clinical Trials: Challenges and Future Opportunities

CHAIRPERSON

Peter SCHÜLER, MD
Vice President, Medical Affairs & Drug Safety, ICON Clinical Research, Germany

Integrating Risk Management with Clinical Development Programmes
Saad A. W. SHAKIR, MB, ChB
Director, Drug Safety Research Unit, UK

Drug Safety Surveillance in Clinical Trials: Concepts for Multicenter Studies
Michael HELLWIG, MD
Senior Group Leader, International Drug Safety Department, Nycomed, GmbH, Germany

Periodic Reporting of Safety Information in Clinical Trials: Current Status in Japan, EU, and US
Shinya YAMAUCHI, BA
Operating Officer
Pharmacovigilance Department, Otsuka Pharmaceutical Co., Ltd., Japan

An Ideal Scenario for Signal Reporting in Clinical Trials
Peter SCHÜLER, MD
Vice President
Medical Affairs & Drug Safety
ICON Clinical Research, Germany

Tools for Enhanced Pharmacovigilance and Signal Detection in Clinical Trials
Wayne Kubick
Senior Vice President for Phase Forward Safety Group, US

Session 0304

Biologics R&D in Chinese Industries

CHAIRPERSON

Peng WANG, PhD
Chief Scientific Officer,
Simcere Pharmaceutical Group, China

Presentation Title to be confirmed
Peng WANG, PhD
Chief Scientific Officer,
Simcere Pharmaceutical Group, China

Presentation Title to be confirmed
David CHEN
Chief Operation Officer
3S Bio, China

China Biotech, Quantity vs Quality
YAN Xiaoqiang, PhD
CSO
Generone Corporation, Shanghai, China

Optimization Strategies of Expression Cell Line Construction to Reduce the Biological Drug Development Risk
Feng GAO, MD, PhD
Chief Operating Officer
Autekbio Inc., China

CONFERENCE DAY 3 | **WEDNESDAY, MAY 19**

8:30 – 12:00 PARALLEL TRACKS – SESSION 4 9:30 – 10:00 REFRESHMENT BREAK

Session 0401

International Experience of Risk Management in Regulatory Agencies and Drug Safety Monitoring

CHAIRPERSON

Dongyi (Tony) DU, MD, PhD
FDA Commissioner's Fellow, US Food and Drug Administration

Prevalence and Cost of Adverse Drug Reactions
Dongyi (Tony) DU, MD, PhD
FDA Commissioner's Fellow, US Food and Drug Administration

Challenges and Prospects in Global Pharmacovigilance – The WHO Perspective
Marie LINDQUIST, PhD
Director, Uppsala Monitoring Centre
WHO Collaborating Centre for International Drug Monitoring, Sweden

Speaker invited
National ADR Center, SFDA, China

Additional speakers invited

Session 0402

Strategy for Conducting Oncology Clinical Trials in Asia Pacific: Case Studies

CHAIRPERSON

Vijay PRABHAKA, MD
Medical Director
PharmaNet, Singapore

Experience of Conducting Successful Oncology Clinical Trials in Asia Using Suitable Case Studies
Emily TAN, MSc
Executive Director
Clinical Operations
PharmaNet, Singapore

Procedure for Conducting Oncology Clinical Trials in Emerging Economy: Report from Vietnam
Speaker invited from Vietnam

Expanded Access Programme: Case Study in AP
Vijay PRABHAKA, MD
Medical Director
PharmaNet, Singapore

Chinese Oncology Patients' Viewpoints of Informed Consent
LI Shuting, MD
Cancer Institute & Hospital Chinese Academy of Medical Sciences, China

Session 0403

Non-clinical Safety Assessment

CHAIRPERSON

Kewen JIN, PhD
General Manager
Charles River Preclinical Services, China

Train to Trust – An Approach in the Opportunity-Challenge Combined Chinese Preclinical Arena
Yi YANG
Head of Preclinical Safety, China R&D;
Director of Drug Safety Evaluation, Global/ sanofi-aventis China

The Development of Chinese GLP Regulations and Practices
CAO Cai
Former Director
Center for Certification, State Food and Drug Administration, China

Challenges of China – GLP Compliance Laboratories Facing Internationalization
Gene HSU
Shanghai National Drug Safety Evaluation Center, China

Emerging Innovative Partnership between Global Pharmaceutical Companies and CROS
Speaker Invited

Session 0404

Capitalizing on the Biologics Revolution through Value-added R&D Partnership in Asia/China

CHAIRPERSON

James CAI, MD
Vice President
Clinical Development, aTyr Pharma, China

Clinical Trial Involving Large Biological Molecules and Bio-Devices
ZHAO Dayao, MD, PhD
Head of Japan-Asia-Pacific Biomedical and Regulatory Affairs, Genzyme Corporation, China

Opportunity and Challenge to Carry on Biologic Clinical Trials in China from Operational Perspectives
WU Yan, MD
Medical and Clinical Development Director, Biogen Idec China

Clinical Trial of Anti-Viral Agent In Viral Hepatitis: No Surrogate
Alex JIANG
Medical Product Manager, Eisai China Inc.

New Era of Biologics in China
Duu-Gong Wu, Ph.D
Executive Director, Consulting Division
PharmaNet, Inc. USA.

12:00 CONFERENCE ADJOURNED

第二届药物信息协会中国年会
从战略到实践 —
引领中国药物创新和开发

会前研习班：2010年5月16日
大会及展览：2010年5月17–19日

会议主席

江宁军 医学博士，哲学博士
赛诺菲–安万特全球研发副总裁兼中国研发中心主任

赵亚军
中国医药国际交流中心主任

会议组委会成员

蔡学钧
美国盘古生物制药公司研发副总裁

曹莉莉
国际食品药品监督管理局中国医药国际交流中心对外合作处处长

戴欣 博士
北京诺华制药有限公司临床开发总监

金克文 博士
上海查士睿华生物医药科技有限公司
总经理

李海燕 主任医师
北京大学临床研究所副所长，北京大学第三医院药物临床试验机构主任

李宁 博士
赛诺菲–安万特中国区集团注册和医学政策高级总监

刘宗范
默克研究所亚太临床数据管理中心经理

苏岭 博士
辉瑞（原惠氏公司）亚太区临床研究组织副总裁

孙丽梅 博士
辉瑞生物制药（中国）有限公司医学部负责人

王鹏 博士
先声药业首席科学官

王春燕 博士
西安杨森制药有限公司临床研发部总监

王武保 博士
默克研究所生物统计与研究决策科学部亚太区运营总监

中国药物的创新和发展日新月异。本次大会将从地区乃至全球的视角帮助参会人员对日愈复杂的监管环境中的研究和策略定位进行探索和交流。

第二届药物信息协会（DIA）中国年会作为一个国际性的中立论坛，参会人员将对中国如何在药物发展中扮演领导角色进行探讨。来自管理机构、企业界和学术界的演讲人将出席并主持本次大会。

本次大会涉及众多领域及学科，将有益于来自管理机构，科研院所、生物制药、临床研究基地、合同研究机构和学术界的专业人士。本次大会将为大家就如何将专业达到更高的阶段及实现人类健康和全球福利而提供平台。

主要分会与议题

- 法规监管事务
- 临床研究
- 药物警戒
- 临床数据管理与统计
- 非临床安全评估
- CMC／GMP
- 研发与生物技术的一般性问题

本会议将有益于从事以下领域的工作人员：

- 法规监管事务
- 临床研究
- 药物研发战略
- 质量保证和质量控制
- 药物安全与药物警戒
- 战略资源与规划
- 生物信息学
- 生物统计学

5月17–19日将提供同传服务

联系方式：

会议咨询：一般咨询与注册，请与刘丹女士联系. Email: dia@diachina.org
展览咨询：请与彭小玲女士联系，Email: dia@diachina.org

合作单位：
国家食品药品监督管理局中国医药国际交流中心

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2010年5月16日，会前研习班

8:30 – 12:30: 研习班 1

通过前瞻性规划、及时评估和有效报告增强药品安全

研习班介绍

随着公众对医疗产品相关安全问题意识的增强，监管机关和制药公司都在更加努力地保证整个产品寿命周期内的药品安全。本讲座旨在介绍从前瞻性规划、及时安全监测与评审以及有效报告的角度介绍控制临床开发期间安全问题的综合性方法。本讲座将采用实例来说明这种三向方法是增强药品安全的。

本讲座的具体论题如下：

- 安全试验设计与分析：安全终点和决定性安全试验、安全分析计划、整合分析
- 利用一种有效工具–数据监视计划(DSP)–早期识别安全信号
- 伦理委员会和DMC的作用
- 有效安全报告

参加者

本次研讨会有特别适合从事药品行业中药品开发和药品营销相关领域工作的人员，以及医治病人和在医疗机构中进行临床试验的职业医师。包括但不仅限于：

- 临床试验研究者
- 临床研究和开发
- 临床研究活动
- 药物安全和药物警戒
- 法规事务
- 生物统计学和数据管理
- 医学写作
- 医疗实践

学习目标

研习班结束时，参加者应该能够：

- 较好地认识到有效的安全监管和报告在药物开发中的重要性
- 取得领先的方法来管理临床开发中的安全问题
  理解管理角度和方向

讲师

江宁军 医学博士 哲学博士
赛诺菲–安万特全球研发副总裁兼中国研发中心主任

陈迅 博士
赛诺菲–安万特中国研发中心统计及编程部总监

James HUNG 博士
美国食品药品管理局药物评估和研究中心生物统计办公室生物统计处一处处长

Robert MAKUCH 博士
USA 美国耶鲁大学医学院生物统计学教授，法规管理项目主任

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

2010年5月16日，会前研习班

8:30 – 12:30 研习班2

医学文献的严格评读

研习班介绍

在当今瞬息万变的世界中，科学家、研究者、医生和学生都会在自己的专业工作中读到多不胜数的医学研究文章。我们怎样才能高效地阅读医学文献并从海量资料中找到有效、有价值的证据呢？本讲座对医学研究文章的要点进行了深入分析，介绍了普遍认可的报告方法。本讲座在简要考察研究设计和统计方法的基础上，采用实例来说明怎样高效、周详而严格地评读医学文献。将在互动模式下对随机化临床试验、疫苗功效试验和药物流行病学研究论文进行讨论。需要在参加讲座前进行阅读和准备。

参与者

本讲座的主要对象包括业内从事药品开发和医药营销相关领域者、从事临床治疗的执业医师以及在保健机构进行临床试验的研究人员。本讲座也将对在工作或研究中需要阅读医学文献的学生、研究者及其他保健专家有所帮助。

- 临床研究与开发人员
- 临床试验研究人员
- 执业医师
- 医学信息与沟通人员
- 医学作者
- 监管人员
- 临床研究活动人员
- 药品安全与药物流行病学者
- 生物统计学者

学习目标

本讲座结束时参与者应当能：

- 说明医学研究文章的要点和优良报告规范；
- 讨论基本健康研究设计和统计方法；
- 更好地理解研究的设计、执行、分析和解释，对其结果的有效性进行严格评估并发现其缺陷、局限性和暗含意义；
- 对好的和差的医学文献进行区分。

讲师

苏岭 博士
辉瑞（原惠氏公司）亚太区临床研究组织副总裁

王武保 博士
默克研究所生物统计与研究决策科学部亚太区运营总监

13:30 – 17:30 研习班3

从FDA／SFDA和行业的角度进行临床试验监测、审核与检查

研习班介绍

近年来，越来越多的全球性临床试验从西方转移到东方，尤其是中国。全球监管机关开始日益关注临床试验的质量。因此，美国食品药品管理局（FDA）或中国国家食品药品监督管理局（SFDA）选择了大量临床试验点并对其进行检查。本讲座有助于听众认识临床试验监测与审核的重要性，并了解审核与检查的执行方式以及监管机关的期望。参与者将了解FDA的外国检查程序、GCP要求、试验点选择标准、检查中常见的问题以及如何为FDA或SFDA的检查做准备。

参与者

- 本研习班适合从事以下行业的人员：
- 临床研究操作人员
- 临床试验研究员
- 临床试验协调员
- 临床研究部门经理
- 质量控制和质量保证人员
- 法规监管事务
- 药物安全合规
- 临床数据管理

学习目标

研习班结束时，参与者应当能：

- 了解一位前FDA审查员采用的审核与检查技术、方法及其常见结果，以便在自己接受检查时做更充分的准备；
- 理解似乎并不重要的结果是怎样使调查员、发起机构和CRO发现严重问题的；
- 学会处理审核与检查中发现的问题.

讲师

Byungja MARCIANTE
美国食品药品管理局中国办事处副总监/研究者

BLAKE R JENSEN 理科学士
INC 质量保证高级总监

李宁 博士
赛诺菲–安万特中国区集团注册和医学政策高级总监

会议日程 2010年5月17日 星期一

8:30 – 9:30 全体大会

致欢迎辞

Richard O. Day, AM, MB, BS, MD, FRACP
药物信息协会主席；
澳大利亚，圣文森(St. Vincent's)医院，临床药理学教授
Paul Pomerantz
药物信息协会全球执行总监

开幕致辞

江宁军 医学博士 哲学博士
赛诺菲–安万特全球研发副总裁兼中国研发中心主任

赵亚军
中国医药国际交流中心主任

主题报告：

待定

9:30 10:00 茶歇

10:00 12:00 全体大会

国家食品药品监督管理局药物管理策略以及优先考虑事项
讲者邀请中

医疗改革和创新
讲者邀请中

通过合作提高研发价值
讲者邀请中

研发创新：中国制药行业的新纪元
讲者邀请中

12:00 13:30 午餐

13:30 – 17:30（茶歇15:00 – 15:30） 平行会议 – 第一场

Session 0101

美国食品药品管理局的最佳法规监管和发展实践

会议主持
李自立 博士
FDA国际校友会(FDAAA)；默沙东（中国）有限公司药审政策研究总监

肿瘤学监管和发展最佳实践
Robert DELAP 医学博士
美国FDA药品评价与研究中心（CDER）前ODEV主任；Celgene公司，副总裁；FDA国际校友会(FDAAA)

抗感染监管和发展最佳实践
Mark J. GOLDBERGER 医学博士 公共卫生硕士.
美国FDA药品评价与研究中心(CDER)，前ODEV主任；副总裁；Abbott FDAAA;

监管和发展最佳实践：美国食品及药物管理局的主题
Florence HOUN 医学博士 公共卫生硕士
前ODE III主任，美国FDA药品评价与研究中心；副总裁

监管和发展最佳实践：肺部/抗感染
Robert J. MEYER 医学博士
前ODE III主任，副总裁；美国FDA药品评价与研究中心；默克公司

Session 0102

临床研究基地的能力开发和管理

会议主持：
待定

专业学术背景下的临床研究人员的培训 – 美国看法
Stephen A. SONSTEIN 教授
东密西根大学临床研究管理系主任/教授

国内临床研究护士培养模式探讨
曹烨
SAE和培训专员
中山大学肿瘤防治中心临床试验研究中心

Investigator Network
讲者邀请中
韩国国家临床研究单位

中国药物临床机构管理模式探讨
胡镜清 主任
中国中医科学院广安门医院临床评价中心主任/国家药物临床试验机构办公室主任，科研处处长

Session 0103

ICH（国际人用药品注册和医药技术要求协调会议）质量指南和启示的更新

会议主持
Chi-wan CHEN 博士
计划委员会成员；执行总监；FDA国际校友会；辉瑞公司

介绍：ICHQ8/9/10–新典范
Chi-wan CHEN 博士
计划委员会成员；执行总监；FDA国际校友会；辉瑞公司

ICH Q8/Q8R 药物发展
Moheb NASR 博士
美国FDA药品评价与研究中心新药质量评估办公室主任

ICH Q9 质量风险管理
Rick FRIEDMAN
美国FDA药品评价与研究中心产品生产质量部合规办公室副主任

ICH Q10药物质量系统
Joseph FAMULARE
Genetech高级总监

ICH Q8/9/10在中国的启示
讲者邀请中
国家食品药品监督管理局药品审批中心

Session 0104

临床数据标准： 您是否合理的进行数据质量测定?

会议主持
Hanming H. TU 理科硕士
总监，Octagon Research Solutions

临床数据质量信息（DQI）：影响临床数据质量的测量结果和因素
Hanming H. TU 理科硕士
MCRP
总监，Octagon Research Solutions

执行标准改善提交数据质量
Paul S. CHUNG, 理科硕士, 工商管理硕士.
Image Solutions 有限公司全球服务执行副总裁

使用CDISC/HL模式和指南的全球数据标准
Shawn WANG 工商管理硕士
MedXview Inc, USA

CRO行业数据管理创新（国内eRDDM）
Xueyou Danny HU, 博士
瑞达医药科技有限公司总经理
执行CDISC SDTM元数据驱动的成本节约
Mike TODD, MA, 理科硕士
Nth Analytics总裁

18:00 – 20:00 联谊招待酒会

会议日程 2010年5月18日，星期二

08:30　12:00（茶歇9:30 – 10:00）　平行会议 – 第二场

Session 0201	Session 0202	Session 0203	Session 0204
回应不断改进的监管环境 会议主持 **张薰文 药学博士** 诺华全球药事法规亚太地区战略发展研究部主任	**在应用研究中确保参与者的安全** 会议主持 **Paul de KONING 博士 医学博士** 安斯泰来制药公司全球发展开发副总裁	**安全信号检测：大海捞针？从法规监管和企业的角度分享经验** 会议主持 **Anna Zhao-WONG, 博士，医学博士** 美国MedRRA MSSO副总监	**现代临床试验设计中的数据关键问题** 会议联席主持 **王武保 博士** 默克研究所生物统计与研究决策科学部亚太区运营总监 **李宁 博士** 赛诺菲–安万特中国区集团注册和医学政策高级总监
药品审评中心的报告 **讲者邀请中** 中国食品药品监督管理局药品审评中心 根据亚太经贸合作组织的和谐宗旨进行更新 **讲者邀请中** APEC亚太经贸合作组织，高温X射线衍射仪(LISF)药物法规协合指导委员会 进度报告，日本厚生劳动省(MHLW)五年计划以及医药品医疗机器综合机构行动方案 **讲者邀请中** 日本医药品及医疗器械管理机构 **另外的讲者邀请中**	首次人用：安全第一 **Paul de KONING 博士 医学博士** 安斯泰来制药全球发展开发副总裁 首次人用：健康的志愿者还是病人？ **Ronald SMULDERS 博士 医学博士** 安斯泰来制药全球发展公司研发部医药总监 在应用研究中采用模型和模仿 **Cornelia WEBER 博士** 上海罗氏制药有限公司，临床药理学 应用研究中的安全生物标志 **Elizabeth ALLEN 博士** 昆泰，科学事务部副组长和科学事务总监	使用MedDRA来辨识潜在安全信号的积极方面和挑战性？ **Anna Zhao-WONG 博士 医学博士** 美国MedRRA MSSO副总监 从法规监管角度看临床试验中的信号检测 **C. George ROCHESTER 博士** 美国食品及药物管理局生物统计学办公室，安全评估协会主任。 从法规监管角度看售后调研中的信号检测 **Mick FOY** 英国药品和保健品监管署，经理 从公司的角度看信号检测 讲者邀请中	适应性和非劣效性指南的统计思考 **H.M. James HUNG 博士** 美国食品药品管理局药物评估和研究中心生物统计办公室生物统计一处处长 在非劣效性试验中进行的保证金选择以及结果解读 **Gang CHEN 博士** 强生肿瘤部领导，统计部总监 多区域临床研究的统计思考 **陈迅 博士** 赛诺菲–安万特中国研发中心统计及编程部总监 讨论小组成员 **沈志华 博士** 罗氏药品开发中国中心生物统计及临床研究管理总监

会议日程 2010年5月18日，星期二

13:30 – 17:30（茶歇 15:00 – 5:30） 平行会议 – 第三场

Session 0301	Session 0302	Session 0303	Session 0304
美国、欧洲、日本和中国全球临床研究和最佳法规监管实践 会议主持 **Alberto GRIGNOLO 博士** 美国PAREXEL咨询公司全球策略与服务部副总裁	**有效的发起人–研究者–CRO–卖家联合以确保临床试验的质量** 会议联席主持 **焦庆安 博士** 赛诺菲–安万特中国研发中心中国临床研究中心总监 **杨佩蓉 博士** 甲骨文（中国）软件系统有限公司生命科学全球事业部产品策略总监	**临床试验间药物警戒：未来机遇与挑战** 会议主持 **Peter SCHÜLER 医学博士** ICON临床研究公司医疗事务和药物安全，副总裁	**中国生物技术的研究和开发** 会议主持 **王鹏 博士** 先声药业首席科学官
如何与美国食品药品管理局开展有效的临床研究 **Alberto GRIGNOLO 博士** 美国PAREXEL咨询公司全球策略与服务部副总裁 欧洲科学建议过程：临床发展成功的路标 **Michael ROZYCKI 博士** 拜耳医药保健公司全球法规事务副总裁 日本药品与医疗器械审批机构(PMDA)有效临床试验咨询 **Satoshi KOIKE 博士** 全球法规事务和安全总监 来自PMDA的讲者邀请中 企业界与CDE在中国对临床发展的有效相互影响 **讲者邀请中** 国家药品监督管理局药品评价中心 另外讲者和讨论小组邀请中	如何提高中国临床研究的效率和质量：赞助方看法 **戴欣 博士** 北京诺华制药有限公司临床开发总监 同源模型/内源模型：资源管理解决方案 **徐宁 博士** 科文斯药品研发（北京）有限公司中国区临床研究部高级总监 在中国引导全球心脏血管研究：国家临床研究协调员的角色 **朱俊 教授** 北京阜外医院 利用临床试验管理系统改善试验效率和试验质量 **杨佩蓉 博士** 甲骨文（中国）软件系统有限公司生命科学全球事业部产品策略总监 讨论小组成员 **李海燕 主任医师** 北京大学临床研究所副所长，北京大学第三医院药物临床试验机构主任	风险管理与临床开发项目相结合 **Saad A. W. SHAKIR 博士** 英国药物安全研究部门总监 临床试验中药品安全监控：多渠道研究概念 **Michael HELLWIG 医学博士** 德国奈科明公司药品安全评价总监 临床试验安全信息定期报告：日本、欧洲和美国的目前情况 **SHINYA Yamauchi** 日本Otsuka制药公司，药物不良反应部门，营运主管 临床试验信号报告的理想方案 **Peter SCHÜLER 医学博士** ICON临床研究公司医疗事务和药物安全，副总裁 用于提高药物安全监测的工具，以及临床试验中的信号检测 **Wayne KUBICK** 美国 Phase Forward 安全集团高级副总裁	演讲题目待定 **王鹏 博士** 先声药业首席科学官 演讲题目待定 **David CHEN** 中国三生制药有限公司 中国生物技术数量和质量 **严孝强 博士** 首席科学官 健能隆(上海)有限公司 制定表达细胞系构建的优化策略以降低生物药品开发风险 **高峰 博士** 首席运营官，中美奥达生物技术有限公司

会议日程 2010年5月19日 星期三

08:30 – 12:00 (茶歇 9:30 – 10:00) 平行会议 – 第四场

Session 0401

监管机构和药物安全监控中的国际风险管理经验
会议主持

会议主持
Dongyi (Tony) DU 博士 医学博士
美国食品药品管理局特别委员

药物不良反应的流行和代价
Dongyi (Tony) DU 博士 医学博士
美国食品药品管理局特别委员

全球药物监测中的挑战和前景 – 世界卫生组织看法
Marie LINDQUIST 博士
世界卫生组织乌普萨拉监测中心， 国际药物监测中心主任

讲者邀请中
国家药品监督管理局药品评价中心

另外的讲者邀请中

Session 0402

在亚洲太平洋进行肿瘤临床试验的策略：案例研究

会议主持
Vijay PRABHAKA 医学博士
法玛特医药总监

在亚洲使用合理的案例成功地进行肿瘤临床试验的经验
Emily TAN 理科硕士
法玛特临床执行总监

在新兴产业中进行肿瘤临床试验的程序：来自越南的报告
计划邀请一位来自越南的监管专家。

扩大处理程序：AP案例分析
Vijay PRABHAKA 医学博士
法玛特医药总监

中国肿瘤患者对临床试验态度的调查
李树婷
伦理委员会秘书
中国医学科学院肿瘤医院

Session 0403

非临床安全评估

会议主持
金克文 博士
上海查士睿华生物医药科技有限公司总经理

信任训练—中国临床前领域中一种机遇挑战共存的方式。
Yi Yang
全球/赛诺菲安万特（中国）药物安全评估总监，中国研究和开发，临床前安全主任

中国药物非临床研究管理规范(GLP)规章和实践
曹彩 教授
国家食品药品监督管理局药品认证管理中心前主任

中国临床前研究的问题和挑战
徐景宏
国家上海新药安全评价研究中心

全球制药公司和合同研究组织之间新兴的合作关系
讲者邀请中

Session 0404

通过亚洲/中国的增值研究和开发合作关系对生物技术革命的资本化

会议支持
蔡学钧 博士
美国盘古生物制药公司研发副总裁

涉及到大生物分子和生物设备的临床试验
赵大尧 博士 医学博士
美国健赞（中国）公司，日本–亚洲–太平洋地区生物医学和副总裁

从操作角性角度看待在中国进行生物临床试验所面临的机遇和挑战
WU Yan 医学博士
美国百健艾迪（中国）公司，医学和临床开发总监

病毒性肝炎治疗中抗病毒剂的临床试验：无替代药品
Alex JIANG
日本卫材(Eisai)药业公司（中国公司），医药产品经理

中国生物制剂新纪元
Duu-Gong WU 博士
美国法玛特咨询部执行总监

12:00 会议结束

2nd DIA China Annual Meeting

Priming China for Drug Innovation and Development: From Strategy to Execution

Meeting I.D. # 10975 – May 16-19, 2010

LOCATION AND VENUE

Crowne Plaza Sun Palace Beijing, Beijing, China, No. 12 Qisheng Middle Street, North-East 3rd Ring Road, Yunnan Dasha, Chaoyang District, Beijing, 100028, P.R. China. The closest airport to this hotel is Beijing Capital International Airport.

CONTACT INFORMATION

For general inquiries and registration, contact Ms. Stephanie Liu at dia@diachina.org. **Exhibits:** Ms. Tina Peng at: dia@diachina.org

Drug Information Association, China office: 11F/1177, Block A, Gateway Plaza, No.18, XiaGuangLi, North Road East 3rd Ring, Chaoyang District, Beijing 100027, P. R. China, Tel: +86-10-59231109 Fax: +86-10-59231090, www.diahome.org, dia@diachina.org

CANCELLATION POLICY: On or before APRIL 30, 2010

Cancellations must be in writing and be received by April 30, 2010. 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 = RMB 500 Nonmember = RMB 500**

** Please carefully submit the meeting application form. As long as we received your application by online or offline, it is confirmed that you will attend the meeting. If you need to cancel your order, you must pay for the administrative fee before April 30, 2010, or you will be charged the full paid after April 30, 2010.*

- **For Visa information and invitation letters, please contact the DIA China Office.**
- **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.**

Online Registration will be available from 2 March – 10 May, 2010, on www.diachina.org. *Click here* to register online.

REGISTRATION FEES FOR CONFERENCE

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

Conference Only *(May 17-19, 2010)*	NONMEMBER	MEMBER
Early-bird*	RMB 4,080 ❑	RMB 3,200 ❑
Standard	RMB 4,480 ❑	RMB 3,600 ❑
Onsite	RMB 4,880 ❑	RMB 4,000 ❑

** Early Bird Closes 9 April 2010*

Join DIA now to quality for the member discount (click here)!

To qualify for the member discount, please submit both the Registration Form and Membership Application accompanied by proof of payment.

MEMBERSHIP
RMB 880 ❑

Discount Fees	NONMEMBER	MEMBER
Government (Full-time)	RMB 2,480 ❑	RMB 1,600 ❑
Charitable Nonprofit/Academia (Full-time)	RMB 3,660 ❑	RMB 2,780 ❑

PRE-CONFERENCE WORKSHOPS *(May 16, 2010)*

Registration Fees

Workshop #1 Enhance Drug Safety through Prospective Planning, Timely Evaluation and Effective Reporting	RMB 1,250 ❑
Workshop #2 Critical Appraisal of the Medical Literature	RMB 1,250 ❑
Workshop #3 Clinical Trial Monitoring, Auditing, and Inspection Workshop – FDA, SFDA,and Industry Perspective	RMB 1,250 ❑
Workshop #1 + Workshop #3	RMB 1,950 ❑
Workshop #2 + Workshop #3	RMB 1,950 ❑

(No member discount)

GROUP REGISTRATION

For workshops #1, #2, and #3 only, register 5 or more people *from the same company,* and receive a 20% discount. ***(No discount on combined workshops).***

- **To take advantage of this offer, please make a copy of this registration form for EACH of the 5 registrants from your company, and return all 5 forms together to DIA China by email to dia@diachina.org or fax to +86-10-59231090.**

• AFTER 10 MAY 2010 ONLY ONSITE REGISTRATION WILL BE ACCEPTED.

** Payment in other currencies will be subject to the financial institution's exchange rate.*

PAYMENT OPTIONS Please indicate payment method.

❑ **BANK TRANSFER**

Payment in the amount of RMB _____ Meeting I.D. #10975

Bank Account: 803020296408091001

Bank Name: Bank of China Beijing Jianguomenwai Sub-branch

Bank Address: No. 24 Jianguomenwai Street, Chaoyang District Beijing, 100004, China.

Payee: KELLEN MANAGEMENT AND CONSULTING (BEIJING) CO., LTD.

SWIFT Code: BKCH CN BJ 110

Bank commission fee should be paid by the registrant.

❑ **CREDIT CARD PAYMENTS BY:**

Cardholder Name _____

Card Issue Bank_____Exp. Date (mm/yyyy)_____

Card #_____ Security Code_____

❑ Visa ❑ Master Card ❑ Other Signature _____

* AMEX and Diners currently are not accepted.

❑ **REQUEST CHINESE OFFICIAL INVOICE (FA PIAO)**

Please complete the invoice request form and send it to the attention of Mr. Tan to qi.tan@diachina.org or fax to +86-10 59231090. After we confirm your payment, the invoice will be mailed to you.

Please check the applicable category: ❑ Academia ❑ Government ❑ Industry ❑ CRO

PLEASE PRINT ALL INFORMATION CLEARLY

Last Name First Name M.I. Full Name in Chinese (If applicable) *Please check one:* ❑ Mr. ❑ Ms.

Job Title Affiliation (Company) ❑ Business Address ❑ Home Address

Address (Please write your address in the format required for delivery to your country.) City Postal Country

Address in Chinese (If applicable)

Telephone Number Fax Number Mobile Number

email (Required for confirmation)

IF FAXING OR MAILING THIS FORM, PLEASE PROVIDE A COPY OF REGISTRANT'S BUSINESS CARD.

Kellen Management and Consulting (Beijing) Co., Ltd. represents DIA in China and provides services.

DIA第二届中国年会
从战略到实践 – 引领中国药物创新和开发
会议编码：#10975， 2010年5月16–19

会议举办场所：
北京新云南皇冠假日酒店
北京市朝阳区东北三环七圣中街12号云南大厦
Tel：(86)1063298888
Fax：(86)1064521889

联系方式：
会议咨询：一般咨询与注册，请与刘丹女士联系
Email：dia@diachina.org
展览咨询：请与彭小玲女士联系
Email： dia@diachina.org

取消注册： 须在2010年4月30日前（含4月30日）
取消注册必须进行书面确认，并确保DIA中国联络处于2010年4月30日之前收到确认。参会注册者如逾期未取消或未参加培训，则注册费不予退还，并应自行取消住宿预订及差旅订票等。
如取消注册，将扣除手续费如下：
会员/非会员：RMB500

- 请谨慎提交注册申请表。一经收到您的在线/ 线下注册信息，均视为有效注册。
- 如在2010年4月30前（含4月30日）取消注册，需扣除部分手续费；逾期将不予退款。

在线注册截止至2010年5月10日
可登录www.diachina.org

会议注册费
含茶歇、午餐及会议资料

年会注册费（5月17–19）	非会员价	会员价
提前注册	RMB4080 ☐	RMB3200 ☐
标准价格	RMB4480 ☐	RMB3600 ☐
现场注册	RMB4880 ☐	RMB4000 ☐

* 提前注册优惠截止4月9日。

现在就加入DIA只需880元， 即享受会员优惠 会员费
立即加入DIA吧！ RMB880 ☐
同时提交会议注册表及会员申请表并付款，即可享受会员优惠。

其他优惠	非会员价	会员价
政府机构(全职人员)	RMB2480 ☐	RMB1600 ☐
非营利组织/学术机构(全职人员)	RMB3660 ☐	RMB2780 ☐

会前研习班注册费(5月16日)

研习班一	RMB1250 ☐
研习班二	RMB1250 ☐
研习班三	RMB1250 ☐
研习班一 + 研习班三	RMB1950 ☐
研习班二 + 研习班三	RMB1950 ☐

(研习班注册费无会员优惠，额满为止)

团体注册优惠 （只适用于研习班一、二、三）
同一家企业五人同时报名同一研习班，可享受8折优惠。(合并注册研习班无优惠)

- 请将五人信息分别填写在单独的注册表内，并通过传真+86 10 59231090或电子邮件dia@diachina.org同时传回。

* 5月10日后只接受现场注册。

* 汇率以中国人民银行当日外汇牌价为准.

付款方式 请注明您的付款方式。

☐ 银行汇款
请即付人民币_____ 会议编码#10975
银行帐号： 803020296408091001
开户行： 中国银行北京建国门外支行
收款人： 科伦管理咨询（北京）有限公司
(请确保全额注册费到帐)

☐ 信用卡支付：
持卡人姓名_____
发卡行_____ 信用卡到期日_____
卡号_____ 安全码_____
☐ 维萨卡 ☐ 万事达卡 ☐ 其它卡 持卡人签名_____

* 目前不接受招商银行卡、美国运通卡和大莱卡支付。

☐ 索取发票
请发送电子邮件至qi.tan@diachinarg或传真至 +86 10 5923 1090
收件人：谭祺 先生
在收到您的全部款项后，我们会将发票邮寄给您。

请核对使用类型 ☐ 学术机构 ☐ 政府机构 ☐ 制药企业 ☐ CRO

请填写下表并保持字迹清晰

姓 _____ 名 _____ 职位 _____ 性别： ☐ 先生 ☐ 女士

单位（公司）名称 _____

中文地址 (请注明地址以便今后能正确邮寄) _____

英文地址 _____ ☐ 公司地址 ☐ 家庭地址

省份及城市_____ 国家 _____ 邮政编码_____

电话 _____ 传真 _____ 手机 _____

电子邮件 (以便通过电子邮件发送确认) _____

如果您传真或邮寄报名表，请提供您的名片或名片复印件。

科伦管理咨询（北京）有限公司在中国境内代表DIA， 并在中国境内为DIA会员提供服务。

2nd DIA China Annual Meeting
Block Code X91
May 16 – 19, 2010 Beijing, China

CROWNE PLAZA
SUN PALACE BEIJING
北京新云南皇冠假日酒店

PLEASE REGISTER ONLINE HERE

Reservation/Confirmation 预订确认

Confirmation No 确认号: _____

公司名称/Company: _____ 日期/Date: _____

联系人/Booker: _____ 传真/Fax: _____ 电话/Tel: _____

MR/MS 先生/女士	Surname 姓	First Name 名			PC NO 优悦会卡号.	
Date of Arrival 到店日期		Date of Departure 离店日期			Nationality 国籍	
Room type	King 大床	Twin 双床	Smoke 吸烟	Non - Smoke 不吸烟	Rate (Per room night) 价格(每间夜)	Remark 备注
Superior Room 高级间					RMB800.00net 人民币 800 元净价	
Deluxe Room 豪华间						
Executive Room 行政间					RMB1200.00net 人民币 1200 元净价	
Executive Suite 行政套间					RMB1800.00net 人民币 1800 元净价	
Arrival Time 到店时间		Flights Details 航班号			Extra Bed □ 加床 RMB350.00 净价	Baby Cot □ 婴儿床

备注 Notices:
- All above room rates are based on per room per night and include in 15% service charge. 以上房价均包含 15%服务费。
- Cut off date for booking is May 10, 2010. 请于 5 月 10 日前预定
- All above room rates are including 1 or 2 American Buffet breakfast at designated venue. RMB98net will be charged as extra breakfast fee. 以上价格均包含 1 份或 2 份自助早餐，如需额外早餐，酒店将加收人民币 98.00 净价/位.
- Rate for in-room high speed internet access at RMB120 net or 24 hours or at RMB3.00 net per minute.
房间内高速上网费用为人民币 3.00 元净价/分钟，人民币 120.00 元净价/天。
- The offer rate only use for the period of this event. 上述房价只适用于本次活动内的时间。

付款方式 Payment 公司 Company A/C: □ 客人自付 Guest(s) A/C: □ 付款备注 Payment Remark

Guarantee □ 不需要 No □ 公司担保 By Company:
担保方式 □ 信用卡/卡号 Yes: By Credit Card No: / /

用车服务 Limousine Service: □ 接机 Pick Up □ 送机 Drop Off □ 接送机 Two Way
航班号 / Flight Number: _____ 人数 / PAX: _____
□ Audi A6 (RMB480.00 per one way) □ Mercedes Benz (RMB900.00 per one way)
□ Buick GL8 (RMB600.00 per one way)

特殊需要 Special Request:

备注 Notices:
- Bookings will be released after 6pm on arrival day if not guaranteed. The AMEX, Visa, Master, Diners Club and JCB card can be accepted for guarantee.
除非信用卡或公司担保，否则预订将保留至当晚 6 点，6 点以后不予保留. 如担保预订取消需当晚 6 点之前通知酒店，否则将收取一晚房费. 酒店接受美国运通卡/维萨卡/万事达卡/大来卡/日本 JCB 卡

Please kindly fill out the form and send it back to the hotel. We will confirm the room according to the availability of the hotel.
请填写完此表格后，根据以下联系方式返回酒店. 根据酒店的可用房间数量进行预定房间的确认。

Reservation Center
预定中心

Crowne Plaza Sun Palace Beijing
北京新云南皇冠假日酒店
No. 12 Qisheng Middle Street North-East 3rd Ring Road.
东北三环七圣中街 12 号
Chaoyang District, Beijing 朝阳区,北京 100028

Tel 电话 (86 10) 6429 8888
Fax 传真 (86 10) 6452 1889
E-mail 邮件 reservation@cpsunpalace.cn

DIA Global Membership Application Form

DIA全球会员申请表

Drug Information Association, 800 Enterprise Road, Suite 200, Horsham, PA 19044-3595, USA

药 物 信 息 协 会
www.diahome.org

1. MEMBER CONTACT INFORMATION 会员信息

Date 日期:

Last Name姓 First Name名 Mobile手机 Sex性别: ☐ Male男 ☐ Female女

Company
公司名称 _____

Job Position职位 _____ Degrees Held学历 _____ Professional Title职称 _____

☐ Business Address工作地址 ☐ Home Address家庭地址 Country国家 _____ Province省 _____ City城市 _____

Mailing Address
邮寄地址 _____ Zip邮编 _____

Phone电话 _____ Fax传真 _____ Email电子邮件 _____

2. PAYMENT METHODS 付款方式

Annual Fee 会员年费: RMB 880

☐ Credit Card
信用卡支付

Download this form, complete and fax to DIA at +86 10 5923 1090 or mail to the address shown on the bottom of this form.
下载填写完本表格后，请传真至+86 10 5923 1090或邮寄至本表格底部所示的地址

Credit Card
信用卡类型 ☐Amex 美国运通卡 ☐Visa 维萨卡 ☐Master 万事达卡 Exp. Date有效期至 _____

Card# 卡号 _____ Signature签名 _____

☐ Bank Transfer
银行电汇

Payment in the amount of RMB880
付款金额为880人民币
Bank Account 账号: **803020206408091001**
Bank Name: Bank of China Beijing Jianguomenwai Sub – branch
开户行名称：中国银行北京建国门外支行
Bank Address: 24Jianguomenwai Street Beijing, 10004, China
开户行地址：中国北京建国门外大街24号

Payee: KELLEN MANAGEMENT AND CONSULTING (BEIJING) LTD.
收款人：科伦管理咨询（北京）有限公司

☐ Request Invoice发票

Email your information to dia@diachina.org or fax to +86 10 5923 1090, Attn: Ms. Stephanie Liu. After we receive your payment, we will send you the invoice and the member card. 请发送电子邮件到dia@diachina.org 或传真到+86 10 5923 1090, 收件人：刘小姐 收到您的付款之后，我们会将发票和您的会员卡邮寄给您。

3. PROFESSIONAL INTEREST AREAS 您感兴趣的专业领域

Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line. Select any others that you wish to receive information on
在下表中，您可以选择您最感兴趣的两个专业领域，并请用“P”标出您的第一选择，用“S”标出第二选择。同时，您也可以选择其它您感兴趣的领域。

____ Academic Health Centers 医学中心
____ Alternative/Herbal Medicine 中药及传统药
____ Biotechnology 生物技术
____ Clinical Data Management 临床数据管理
____ Chemistry 化学
____ Clinical Laboratory Data 临床试验数据
____ CMC 化学、生产、质控
____ Clinical Safety/Pharmacovigilance 临床安全/药物安全监测
____ Clinical Research & Development 临床研发
____ Clinical Supplies 临床(试验)用药供给
____ Dictionaries/Data Standards 字典/数据标准
____ Devices 器械
____ Document Management 档案管理
____ Finance 财务
____ e-Clinical 电子临床
____ GCP 药品临床试验管理规范
____ Generic Manufacturing 仿制生产
____ GLP 药品优良实验室规范
____ GMP 药品优良生产管理规范
____ Information Management 信息管理
____ Investigator Site 研究机构
____ Information Technology/e-Business 信息技术/电子商务
____ Marketing/Advertising 市场/广告
____ Medical Communications/Information 医学交流/信息
____ Managed Healthcare 健保服务
____ Manufacturing: Drug Substance, Drug Product, Packaging 生产、药物成份、药物产品、包装
____ Medical/Scientific Writing 医学/学术写作
____ Non-clinical Safety & Efficacy/Toxicology 药物非临床安全和有效性研究/毒理研究
____ Natural Health Products 天然保健产品
____ Outsourcing/Virtual Development 外包/虚拟开发
____ Over-the-Counter 非处方药
____ Pharmaceutics 制药学
____ Professional Development 职业发展
____ Pharmacoepidemiology/Quality of Life/Health Economics/Outcomes Research 流行病药物学/生活质量/医药经济学/结果研究
____ Pharmacology 药理学
____ Pharmacokinetics/Metabolism/ Pharmacodynamics 药代动力学/药物代谢/药效动力学
____ Project Management 项目管理
____ Public Policy/Law 公共政策/法律法规
____ Quality Control/Quality Assurance 质量控制/质量保障
____ Regulatory Affairs/Policy/Drug or Device Approval/ GRP 法规事务/政策/药品及仪器械审批/药物优良审评规范
____ Research & Development/ Strategic Issues 研发/战略
____ Statistics/Biostatistics/Modeling 统计/生物统计/造型术
____ Training 培训
____ Validation 验证

Membership is not refundable or transferable. 会员费一旦支付将不予退还，会员资格不可转让

DIA Member Profile DIA会员个人信息

Profile answers help DIA provide you with information that is appropriate to your needs.
提供以下信息有助于我们更好为会员提供适合的会议内容。请在填写完您的申请表后，回传给我们。

4. How long have you worked in this industry? Select one. 您从事这个行业已经多久了？（请选择一项）

☐ <1 year 1年	☐ 1-2 years 1-2年	☐ >2-3 years 2-3年以上	☐ 4-6 years 4-6年	☐ 7-10 years 7-10 年
☐ 11-15 year 11-15年	☐ 16-20 years 16-20年	☐ 21-25 years 21-25年	☐ >25 years 25年以上	

5. How long have you been in your current position? Select one. 您在这个岗位上多久了？（请选择一项）

☐ <1 year 1年	☐ 1-2 years 1-2年	☐ >2-3 years 2-3年以上	☐ 4-6 years 4-6年	☐ 7-10 years 7-10 年
☐ 11-15 year 11-15年	☐ 16-20 years 16-20年	☐ 21-25 years 21-25年	☐ >25 years 25年以上	

6. What is the year of your birth? 您出生的年份是_____(optional，可不填)

7. What is the highest level of education you have completed? Select one. 您的最高学历？（请选择一项）

☐ Doctorate 博士	☐ MD 医学博士	☐ PharmD 药学博士	☐ Masters 硕士	☐ Bachelors 学士
☐ Associate 大专	☐ Technical Specialty Training 专业技术训练			

8. What is your current work setting? Select one. 您目前的工作是在哪个领域？（请选择一项）

Industry 行业	Government 政府	Support /Products 服务或产品	Academic Institutions 学术机构	Health Care Delivery 卫生机构
☐ Pharmaceuticals制药	☐ Regulatory法规	☐ CRO / CSO / MSO	☐ University / College大学/学院	☐ Hospital医院
☐ Devices器械	☐ Health Agency卫生管理机构	☐ Marketing / Advertising市场/广告	☐ Academic Health Center医学中心	☐ MCO / HMO
☐ Biotechnology生物技术	☐ Other 其它	☐ Independent Consultant独立咨询人员	☐ Technical Training School技术培训中心	☐ Primary Care开业医生/诊所
☐ Other 其它		☐ Staffing / Personnel 职员/人员	☐ Full Time Student全日制学生	☐ Other 其它
		☐ Information Technology信息技术	☐ Other 其它	
		☐ Other 其它		

9. What is the size of the organization you work for? Select one. 您目前所工作单位的规模是：（请选择一项）

☐ 1 – 50 employees 1 – 50 名员工	☐ 51 – 500 employees 51 – 500名员工	☐ 501 – 5,000 employees 501 – 5,000名员工	☐ 5,001 – 15,000 employees 5,001 – 15,000名员工
☐ 15,001 – 50,000 employees 15,001 – 50,000名员工	☐ More than 50,001 employees 超过 50,001名员工		

10. What is your current level of organizational responsibility? Select one. 您的工作职责是：（请选择一项）

☐ Responsible for overall organizational functions 负责公司综合业务（如：战略导向、质量/培训管理、预算制定与控制、 人员聘用管理）
☐ Responsible for departmental, divisional or group functions 负责部门或工作组业务（如：团队管理、项目执行、项目管理）(i.e., Supervise Team, Event Execution, Project Leader)
☐ Responsible for specialized function or a job within a group or division 负责专项工作（如：团队成员、专员）(i.e., Team Member, Specialist)
☐ Other 其它

11. What is the primary focus of your full-time work? Select one. 您最重要的一项工作是：（请选择一项）

☐ Discovery 发现	☐ Development 开发	☐ Approval / Licensing 审批/许可	☐ Manufacturing 生产
☐ Utilization 应用	☐ Policy 政策	☐ Across Multiple Areas 跨领域	☐ Sales / Marketing 销售/市场

Submit this form to the Drug Information Association 提交表格至DIA

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