

药物信息协会临床数据管理研讨班

GCP规范指导下的临床研究数据质量和完整性： 从受试者招募到数据申报

2011年10月25-26日

中国，上海



会议主席

刘川 博士

Medidata Solutions Worldwide大中华地区发展总监

组织委员会

刘宗范

默沙东（上海）医药咨询有限公司全球临床数据管理中心亚太区总监

王武保 博士

美国默克公司默克研究实验室生物统计与研究决策科学部亚太区总监

杨佩蓉 博士

甲骨文软件系统有限公司生命科学全球事业部产品策略总监

姚晨 教授

北京大学临床研究所副所长

北京大学第一医院药学统计室主任

内容概览

这将是首次在中国系统和全面介绍按照GCP原则临床研究数据质量和完整性管理的基本知识的研讨班。通过这期研讨班，您将会对数据管理生命周期的原则和程序，以及数据过程与药物研发，包括计算机化系统，药政标准，计算机化系统的认证体系，数据准备和申报的关系有所了解，对于如何计划和实施数据管理计划和监督临床研究生命周期中数据完整性和准确性也将会有所掌握。同时，本期研讨班也将对电子系统中临床数据管理作用和策略有所探讨。

学习内容

此期研讨班您将会学习到：

- 药政规范和标准的概述及其与数据管理科学的关系
- 临床数据管理员的经验和角色，以及在临床研究的新设计中数据管理面临的挑战/机会关系
- 数据管理专业人员与统计师，程序员，其他临床专业人员之间的有效交流和互动
- 按照GCP标准数据质量和完整性的基本概念和期许，以及对数据管理的改善
- 试验方案的撰写和病例记录报告的设计
- 开发电子病例记录报告的最佳实践和电子系统的认证
- 临床研究中数据管理的文件准备
- 临床研究报告/通用技术文件（CSR/CTD）的完成
- 临床研究中医疗记录可靠性的验证
- 电子申报过程 - 从设计到实施
- 电子数据采集系统的扩充和整合

学习目标

在本期研讨班结束时，您应当能够：

- 理解药政规范和GCP实践对数据管理的影响
- 更深入领会数据管理员的角色变化和挑战，以及在电子系统的环境下更有效地管理和交流数据管理
- 概述出数据管理在临床方案审阅和病例记录报告设计中的工作重点所在
- 理解数据管理工作中交流，标准化和文档的重要性
- 学会数据管理运营和程序的“最佳实践”
- 对电子系统的扩充和在业界的运用有所认识
- 为自己更积极地对临床试验项目有所作为做好准备

参会人员

- 临床试验数据管理人员
- 临床项目管理人员
- 临床试验监查员
- 临床研发专业人员
- 临床研究生物统计师
- 临床研究计算机系统用户
- 临床稽查人员
- 临床质量保证和质量控制专业人员
- 临床药政事务专业人员
- 临床研究者和研究协调员
- 临床信息技术专业人员
- 临床研究编程人员

DIA China

Rm. 1155, Block A, Gateway Plaza
No. 18 XiGuangLi, North Road, East Third Ring
ChaoYang District, Beijing, 100027, China

Worldwide Headquarters

Horsham, PA, USA

Regional Offices

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



www.diahome.org

第一天 10月25日 · 星期二

7:30 – 8:00 会议注册及早餐

8:00 – 9:30 全球规范概述及其对数据管理科学的影响

介绍药政规范及标准，例如电子病历、电子签名、审计追踪、临床数据管理系统验证、欧盟93/99/EC指令、电子签名及认证服务的相关法律 (JP)、ICH-E6、CDISC、ALCOA规则、数据隐私保密 (HIPPA) 等，及其对临床数据管理的影响

杨佩蓉 博士

甲骨文软件系统有限公司生命科学全球事业部产品策略总监

9:30 - 10:30 临床数据管理者的角色及面临的挑战

概述在药物研究与开发中临床数据管理者的角色、责任、活动与机会，包括研究设计、试验方案的撰写、研究的启动及新型创新设计 (如适应性设计、多区域临床试验)

丁力

赛诺菲-安万特亚太地区临床运营总监

陆彬

赛诺菲-安万特床运营部 临床试验运营经理

黄钦 MD, MPH, PhD

中国国家药监局药品审评中心生物统计部长

李卫, 教授、博导

卫生部心血管病防治研究中心生物统计部主任，中国医学科学院阜外心血管病医院
国药局药物及医疗器械审评专家

10:30 – 10:45 茶歇

10:45 – 12:00 临床试验数据/方案与数据管理和相关数据管理计划

概述临床试验数据的类型、定义及目标以及试验方案设计与数据管理的关系。讨论如何准备并撰写数据管理计划和统计分析计划

颜崇超 博士

上海临床医药研究中心临床数据管理高级总监

12:00 – 13:00 午餐

13:00 – 14:30 试验方案的撰写及病例报告表的设计

介绍如何开始并撰写满足全球药政规范的完整的试验方案，如何从试验方案推导到病例记录报告/电子病例记录报告以及在哪些试验活动中数据管理者的责任

姚晨 教授

北京大学临床研究所副所长
北京大学第一医院药学统计室主任

14:30 - 15:30 数据管理中的文件准备及数据库管理

概述在临床研究中必备哪些文件以及数据管理在其中扮演的角色。探讨数据库结构、类型、编辑审核的设立以及数据管理中的法规要求、数据库结构及活动

陈朝华

辉瑞中国研发中心全球临床数据服务部门负责人

Lily ZHAO

副总监，数据管理，美斯达（上海）医药开发有限公司

任建军

辉瑞(中国)研发中心全球临床数据服务部门高级运营支持经理

李卫, 教授、博导

卫生部心血管病防治研究中心生物统计部主任，中国医学科学院阜外心血管病医院；
国药局药物及医疗器械审评专家

刘敏芝 博士

合伙人，副总经理，美斯达（上海）医药开发有限公司

15:30 – 15:45 茶歇

15:45 –16:45 数据管理中的文件准备及数据库管理

概述数据管理活动、类型、方法、数据流程、数据查询注意事项 (时序报告、类型及规格) 及对数据追踪活动、关闭程序及活动与质量保证和标准化事宜

刘宗范

默沙东（上海）医药咨询有限公司全球临床数据管理中心亚太区总监

16:45 – 17:30 临床研究中医疗记录可靠性的验证

介绍在临床研究中验证并协调医疗记录过程中的质量保证及方法

Earl Hulihan

美国Medidata Solutions 全球公司法规事务部高级副总裁兼Peach项目主任

第二天 · 10月26日 · 星期三

7:30 - 8:00 早餐

8:00 - 9:30 建立和管理电子病例记录报告的最佳实践

概述在建立电子病例记录报告过程中的管理活动、类型和考虑要素，以及在临床研究的运作和实施中整合并提升EDC工具的最佳考虑，同时还将讨论到电子系统的验证

刘川 博士
Medidata Solutions Worldwide大中华地区发展总监

9:30 - 10:30 从数据库锁定到临床研究报告的过渡任务

综述数据库锁定期间和临床研究报告启动过程中各种程序及其责任。讨论在临床研究报告和电子通用技术文件的综合分析中非盲审、违规试验方案执行的备忘录、数据采集分析及数据表、清单和图表的准备。对盲审的过程、违规方案执行的鉴定、数据问题报告和清理与数据库重新锁定等话题进行概述

张子豹 博士
PPD中国生物统计部副总监

王武保 博士
美国默克公司默克研究实验室生物统计与研究决策科学部亚太区总监

10:30 - 10:45 茶歇

10:45 - 12:00 电子申报过程——从设计到实施

介绍电子申报系统的结构、活动、最佳策略和程序、考虑要素、法规要求及质量保证

Paul CHUNG
CSC Life Sciences方案监管部业务总监

12:00 - 13:00 午餐

13:00 - 14:00 临床数据的质量及完整性

对数据质量及完整性定义、预期和重要性的介绍及其在GCP标准监管下的完善。介绍临床研究中数据管理质量体系的概念。此外，还将描述根据GCP标准的数据质量和完整性要求，如何准备和执行试验数据管理过程中稽查和视察的最佳策略和实践。探讨源数据（如临床项目、方案、有效及安全记录的保留及申报等）的稽查问题也将被探讨。

Earl Hulihan
美国Medidata Solutions 全球公司法规事务部高级副总裁兼Peach项目主任

刘川 博士
Medidata Solutions Worldwide大中华地区发展总监

14:00 - 15:00 药政机构临床数据审阅实践的常用模式

描述药政申报和审阅过程中，评审员通常采用的临床数据评价的常用模式，包括安全性数据审阅，发现数据问题的验证和核查，以及数据质量和完整性，发现欺诈数据的方法等方面。

Eric HERBEL
Integrated Clinical Systems公司总裁

15:00 - 15:15 茶歇

15:15 -16:15 互动交流及问答

对数据管理专业人员与统计师，程序员，其他临床专业人员之间有效交流和互动的特别介绍及战略探讨

王武保 博士
美国默克公司默克研究实验室生物统计与研究决策科学部亚太区总监

16:15 - 17:30 案例分析与问答

咨询与问答：数据经理的日常工作

刘宗范
默沙东（上海）医药咨询有限公司全球临床数据管理中心亚太区总监

颜崇超 博士
上海临床医药研究中心临床数据管理高级总监

17:30 会议结束

Quality and Integrity of Clinical Study Data in the Compliance with GCP: From Patient to Data Submission

October 25-26, 2011
Shanghai, China



PROGRAM CHAIRPERSON

Daniel LIU, PhD

Director, China Development
Medidata Solutions Worldwide, China

PROGRAM COMMITTEE

Joanne LIU

Regional Director, Asia Pacific Data Management Center
Global Data Management & Standards
Merck & Co., Inc, China

William WANG, PhD

Head of Asia Pacific Hub, Biostatistics and Research
Decision Sciences (BARDS) Merck Research Laboratories
Merck & Co., Inc, China

Rachel YANG, MD, PhD

Director, Product Strategy, Health Sciences Global
Business Unit, Oracle Corporation

Chen YAO, Professor

Vice Director, Peking University Clinical
Research Institute, Head of Department of Biostatistics
Peking University First Hospital, China

WHO SHOULD ATTEND

- Trial data managers
- Trial project managers
- Trial monitors
- Trial quality assurance and quality control professionals
- Biostatisticians
- Clinical computer system users
- Trial auditors
- Clinical development professionals
- Clinical regulatory affairs professionals
- Clinical researchers and study coordinators
- Clinical information technology professionals
- Trial programmers

DIA China

Rm. 1155, Block A, Gateway Plaza
No. 18 XiGuangLi, North Road, East Third Ring
ChaoYang District, Beijing, 100027, China

Worldwide Headquarters

Horsham, PA, USA

Regional Offices

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

Gain Insight into the Quality and Integrity Process of Clinical Data in a GCP Environment.

This workshop will provide you with principles and processes involved in the data management life cycle and relationship of data process system with the drug development, including computerized systems, regulatory standards, computerized systems validation, data preparation and submission, as well as how to plan and conduct a data management plan and monitor data integrity and accuracy in the clinical study life cycle. You will also learn the role that clinical data management plays in the eSystem world.

FEATURED TOPICS

- Regulatory environment and standards and how they relate to data management disciplines
- Experiences and roles of clinical data managers
- Data management-related challenges/opportunities with new innovative designs in clinical research
- Effective communications and interactions between data management professionals and statisticians, programmers, and other clinical professionals
- Basic concepts and expectations of data quality and integrity and their improvements governed by GCP standards
- Protocol development and CRF design
- Best practice in eCRF development and e-systems validation
- Document preparation of data management in clinical studies
- CSR/CTD completion
- Validation of the reliability of medical records in clinical study
- E-submission process - from design to implementation
- EDC system enhancement and integration

LEARNING OBJECTIVES

At the end of the workshop, participants should be able to

- Understand the regulations and GCP practices as they impact data management
- Describe in-depth the changing role and challenges of the data manager as well as more efficient management and communication of data management in the e-system world
- Outline the DM focus on protocol review and CRF design
- Understand the importance of communication, standardization and documentation in the DM prospective
- Learn the "best practice" for DM operation and process
- Identify e-system enhancements and applications in the industry
- Prepare the participants to contribute positively to a project and implementation of group sequential design and analysis (interim analysis)
- Understand the common statistical approaches to multiple comparisons and multiple endpoints in the context of controlling overall false positive finding rate

DAY 1 | TUESDAY, OCTOBER 25

7:30 – 8:00 REGISTRATION AND BREAKFAST

8:00 – 9:30 SESSION 1

OVERVIEW OF GLOBAL REGULATION AND ITS IMPACT TO DM DISCIPLINES

Introduction of regulatory environment and standards, such as (e-records and e-sig, audit trail, validated CDMS, EU directive 93/99/EC, law concerning electronic signatures and certification service (JP), ICH-E6, CDISC, ALCOA rule, data privacy (HIPPA))etc., and their impacts to clinical data management

Rachel YANG, MD, PhD

Director, Product Strategy, Health Sciences Global Business Unit, Oracle Corporation, China

9:30 - 10:35 SESSION 2

ROLES AND CHALLENGES OF CLINICAL DATA MANAGERS

Outlines of the roles, responsibilities, activities, opportunities of DM in drug research and development including study design, protocol development and study initiation and new innovative designs as well (e.g., adaptive design, multi-regional trials)

Li DING (SESSION CHAIR)

Director and Head, Asian Pacific Trial Operation, Sanofi-Aventis, China

Christine LU

Clinical Trial Operation Manager, Clinical Science & Operation - Trial Operation, Sanofi-Aventi, China

PANEL DISCUSSION: Speakers and**Qin HUANG, MD, MPH, PhD (PANELIST)**

Deputy Director(Acting), Office of Biostatistics, CENTER FOR DRUG EVALUATION, SFDA

Wei LI, Professor

Director, Division of Biometrics, National Center for Cardiovascular Diseases, Cardiovascular Institute & Fuwai Hospital (CAMS & PUMC). Advisor of SFDA (Drug / Medical Device)

10:35 – 10:45 REFRESHMENT BREAK

10:45 – 12:00 SESSION 3

CLINICAL TRIAL DATA/PROTOCOL VERSUS DATA MANAGEMENT AND RELEVANT DM PLAN

Outline types, definition and objectives of trial data, and relationship of trial protocol design to data management. How to prepare and write data management plan (DMP) and statistical analysis plan (SAP) will be discussed

Charles YAN

Senior Director, Clinical Data Management, Shanghai Clinical Research Center (SCRC)

12:00 – 13:00 LUNCH BREAK

13:00 – 14:30 SESSION 4

PROTOCOL DEVELOPMENT AND CRF DESIGN

Introduction how to initiate and develop a full protocol meeting global regulatory expectations and be derived from the protocol to a CRF/eCRF as well as the DM responsibilities in these trial activities

Chen YAO

Vice Director, Peking University Clinical Research Institute, Head of Department of Biostatistics, Peking University First Hospital, China

14:30 - 15:30 SESSION 5

PREPARATION OF DOCUMENTATION AND DATABASE BY DM

Overview what documents are necessary to be prepared in the clinical study and what roles of DM play in. Database structure and types as well as edit check establishment will be addressed. Regulatory requirements, database structures and database activities by DM will be discussed, too

Jessie CHEN (SESSION CHAIR)

Head of Global Clinical Data Services, Pfizer (China) Research & Development Co., Ltd.

Lily ZHAO, MD (DOCUMENTATION)

Associate Director, Data Management, MacroStat (China) Clinical Research Co., Ltd.

Jay REN, MD (DATABASE)

Senior Operation Support Manager, Pfizer (China) Research & Development Co., Ltd.

PANEL DISCUSSION: Speakers and**Wei LI, Professor**

Director, Division of Biometrics, National Center for Cardiovascular Diseases, Cardiovascular Institute & Fuwai Hospital (CAMS & PUMC). Advisor of SFDA (Drug / Medical Device)

Minzhi LIU, PhD

Partner, Deputy Managing Director, MacroStat(China) Clinical Research Co., Ltd.

15:30 -15:45 REFRESHMENT BREAK

15:45 – 16:30 SESSION 6

DATA ENTRY, DATA IMPORT, DATA EDITING, DATA TRACKING, DATA CODING AND DATABASE CLOSING

Overview of activities, types, methods, data flow, data query considerations (timing reports, types and specifications), items to data tracking activities, closing process and activities as well as quality assurance and standardization

Joanne LIU

Regional Director, Asia Pacific Data Management Center, Global Data Management & Standards, Merck & Co., Inc., China

16:45 – 17:30 SESSION 7

VALIDATION OF RELIABILITY FOR MEDICAL RECORDS IN CLINICAL STUDY

Introduction of methodologies and quality assurance to verify and reconcile the medical records in clinical study

Earl HULIHAN

Senior Vice President, Regulatory Affairs Medidata Solutions, Inc., USA

DAY 2 | WEDNESDAY, OCTOBER 26

7:30 – 8:00 BREAKFAST

8:00 – 9:30 SESSION 8

BEST PRACTICE IN ECRF DEVELOPMENT AND MANAGEMENT

Outlines of management activities, types and consideration elements when an eCRF is build up and best considerations to integrate and enhance EDC tools in the operation and implementation of the clinical studies. Validation of e-system will be addressed

Daniel LIU

Director, China Development, Medidata Solutions Worldwide, China

9:30 – 10:30 SESSION 9

TRANSITION TASKS FROM DATABASE LOCK TO CSR

Overview varieties of the process and responsibilities in the period of data base lock and initiation of clinical study reports (CSR). The preparation of un-blinding verification, protocol violation memo, analysis datasets, tables, listings and figures (TLFs) for CSR and integrated analyses in eCTD will be discussed. The process of blinding review, protocol violations determination, data issue report and cleaning, and database re-lock will be overviewed

Zibao ZHANG

Associate Director, Biostatistics, PPD China

William WANG, PhD

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

10:35 – 10:45 REFRESHMENT BREAK

10:45 – 12:00 SESSION 10

E-SUBMISSION PROCESS – FROM DESIGNING TO IMPLEMENTATION

Introduction the structure, activities, best strategies and process, critical elements to be considered, regulatory requirements and quality assurance of e-submission system

Paul CHUNG

Solution Practice Director, Regulatory Solutions Group, CSC Life Sciences

12:00 – 13:00 LUNCH BREAK

13:00 – 14:00 SESSION 11

PROTOCOL DEVELOPMENT AND CRF DESIGN

Introduction of definitions, expectations and importance of data quality and integrity and their improvements governed by GCP standards. The concepts of quality system of data management in the clinical studies will be mentioned. Moreover, describe the best strategy and practice to prepare and conduct audit and inspection of trial data management base on the quality and integrity of data convention under GCP standards. Audit of source data (e.g. clinical program, protocol, retention and reporting of efficacy and safety records etc) will be discussed.

Earl HULIHAN, Professor

Senior Vice President, Regulatory Affairs Medidata Solutions, Inc., USA

Daniel LIU, PhD

Director, China Development, Medidata Solutions Worldwide, China

14:00 – 15:00 SESSION 12

TYPICAL USE PATTERNS OF CLINICAL DATA REVIEW OF REGULATORY AGENCIES

The presentation is a survey of common patterns of use of clinical data review by reviewers when looking at data included with regulatory submissions. Topics include aspects of thorough safety review, validation and verification of findings, investigation of data quality and integrity including fraud detection

Eric HERBEL

President, Integrated Clinical Systems, Inc.

15:00 – 15:15 REFRESHMENT BREAK

15:15 – 16:15 SESSION 13

Q&A AND INTERACTIONS

Special introduction and discussions of strategies for effective communications and interactions of DM professionals with statisticians, programmers, clinical and other professionals

William WANG, PhD

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

16:15 – 17:30 SESSION 14

Q&A AND CASE STUDY

Q&A and practicum

Joanne LIU

Regional Director, Asia Pacific Data Management Center, Global Data Management & Standards, Merck & Co., Inc., China

Charles YAN

Senior Director, Clinical Data Management, Shanghai Clinical Research Center (SCRC)

药物信息协会 (DIA) 临床数据管理研讨班

会议编码: #11979 · 2011年10月25-26日

中国 · 上海 · 光大会展中心国际大酒店

会议举办场所:

上海光大会展中心国际大酒店
上海市漕宝路66号
Tel: +86 21 64842500
Fax: +86 21 64845595

联系方式:

会议咨询: 请与谢飞先生联系
DIA China
北京市朝阳区东三环北路霞光里18号佳程广场A座11层1155室,
100027
电话: +86 10 5923 1109 传真: +86 10 5923 1090
E-mail: fei.xie@diachina.org

取消注册: 须在2011年10月21日前(含10月21日)

取消注册必须进行书面确认 (Email 或传真):
凡已注册并付款者, 在2011年10月21日之前取消注册, 须按注册规定扣除
手续费RMB500
凡已注册并付款者, 若逾期未确认取消或未参加培训者, 其缴纳的注册全
额将不予退还
凡已注册但未付款者, 在2011年10月21日之前取消注册, 须按注册规定缴
纳手续费RMB500
凡已注册但未付款者, 若逾期未确认取消或未参加培训, 仍须按注册规定
全额缴纳注册费
参会注册者应自行取消住宿预订及差旅订票等

▶ 同意取消注册条款, 请在下方横线处签名

参会代表签名 _____

在线注册截止至2011年10月21日
可登录 www.diachina.org, 或 [点击此处](#)

会议注册费

含茶歇、午餐及会议资料

培训班注册费

	非会员价	会员价
提前注册 (07月22日-10月13日)	RMB 2680 <input type="checkbox"/>	RMB 1800 <input type="checkbox"/>
标准价格 (10月14日-10月21日)	RMB 3180 <input type="checkbox"/>	RMB 2300 <input type="checkbox"/>
现场注册 (10月22日-10月24日)	RMB 3680 <input type="checkbox"/>	RMB 2800 <input type="checkbox"/>

* 提前注册价格优惠截止至2011年10月13日

现在就加入DIA只需880元, 即享受会员优惠

[立即加入DIA吧!](#)

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/学术机构(全职人员)	RMB2380 <input type="checkbox"/>	RMB1500 <input type="checkbox"/>

*选择银行转帐方式进行支付的参会者请注意:

如果您选择的是早期优惠注册价格, 请您务必确保DIA中国办公室于2011年10月13日前收到您的注册费用;

如果您选择的是标准注册价格, 请您务必确保DIA中国办公室于2011年10月21日前收到您的注册费用。

* 2011年10月21日后只接受现场注册。

***参会者同时注册统计研讨班, 将享受10%优惠**

团体注册优惠: 同一公司4人同时注册, 第5人免费参会! 5人必须在同一时间注册并付款才可享受该优惠。免费参会仅限会议不包括DIA会员费。享受优惠的参会者可以替换, 但因会员与非会员的差别会产生一定的费用。团体注册优惠只接受线下注册, 不与其他优惠共用。请将贵公司享有此优惠的每位参会者的注册表填好后回传给DIA。

此表格为团体注册的一部分, 请在下面列出贵公司其他四个参会者的名字

- _____
- _____
- _____
- _____

索取发票

请发送电子邮件至 qi.tan@diachina.org 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。

付款方式 请注明您的付款方式。* 汇率以中国人民银行当日外汇牌价为准。

银行汇款

请即付人民币 _____ 会议编码 #11979

银行帐号: 333757195112

开户行: 北京市朝阳区支行营业部

银行地址: 北京市朝阳区东三环北路霞光里18号佳程广场A座一层

收款人: 迪亚恩(北京)医药信息咨询有限公司

SWIFT: BKCH CN BJ 110

(请确保全额注册费到账)

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 境内信用卡

持卡人签名 _____

* 请注意目前只接受下列信用卡:

境外信用卡: 维萨卡和万事达卡

境内信用卡: 中国银行, 中国建设银行, 中国工商银行, 广东发展银行, 兴业银行, 华夏银行, 招商银行电话银行

请核对使用类型 药厂 政府部门 科研院校 实验室/CRO/CSO 医疗机构-医院/诊所 咨询公司 其他

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)有限公司为DIA中国提供会议服务

DIA China Annual Workshop for Clinical Data Management

Meeting I.D. # 11979 -October 25-26, 2011

Shanghai, CHINA

TRAVEL AND HOTEL The most convenient airport is Shanghai Hongqiao Airport and attendees should make airline reservations as early as possible to ensure availability. Shanghai Everbright Convention & Exhibition Center International Hotel, Shanghai, China, is holding a block of rooms at the reduced rate below for the DIA event attendees. Room availability at this rate is guaranteed only until the block is filled.

Standard Rate

RMB 450

Attendees must make their own hotel reservations. Contact the Shanghai Everbright Convention & Exhibition Center International Hotel by telephone at +86 21 64842500 and by fax at +86 21 64845595 and mention the DIA event. The hotel is located at 66 Cao Bao Road, Xuhui District Shanghai, Postcode:200235, P.R. China.

Drug Information Association, China office: 11F/1155, 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 OCTOBER 21, 2011

Cancellations must be made in writing and received by October 21, 2011, in order to receive a full refund minus the administrative fee of Member = RMB 500 Nonmember = RMB 500, before the cancellation date. Registrants who do not cancel in writing by the deadline date and do not attend the event will be responsible for paying the full registration fee. Registrants are also responsible for cancelling their own hotel and airline reservations. 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.

I agree with the terms of the cancellation policy.

Signature Participant _____

**Online Registration will be available from
July 22 - October 21, 2011, 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.

	NONMEMBER	MEMBER
Industry Early-bird* (July 22 - October 13)	RMB 2680 <input type="checkbox"/>	RMB 1800 <input type="checkbox"/>
Industry Standard (October 14 - October 21)	RMB 3180 <input type="checkbox"/>	RMB 2300 <input type="checkbox"/>
Industry Onsite (October 22 - October 24)	RMB 3680 <input type="checkbox"/>	RMB 2800 <input type="checkbox"/>

* Early Bird Closes October 13, 2011

Join DIA now to qualify 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.

Discount Fees	NONMEMBER	MEMBER
Nonprofit/Academia/Government (Full-time)	RMB 2380 <input type="checkbox"/>	RMB 1500 <input type="checkbox"/>

• AFTER OCTOBER 21, 2011, ONLY ONSITE REGISTRATION WILL BE ACCEPTED.

*** PARTICIPANTS WHO ALSO REGISTER FOR STATISTICAL WORKSHOP, WILL RECEIVE A 10% DISCOUNT**

GROUP DISCOUNTS* Register 4 individuals from the same company and receive complimentary registration for a 5th! **All 5 individuals must register and prepay at the same time - no exceptions.** DIA will apply the value of the lowest applicable fee to this complimentary registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred. **Group registration is not available online and does not apply to the already-discounted fees for government or charitable nonprofit/academia.** To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

Please indicate that this form is part of a group registration by checking this box and list below the names of the other four registrants from your company.

1. _____
2. _____
3. _____
4. _____

* 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. #11979

Bank Account: 333757195112

Bank Name: Bank of China, Beijing Chaoyang Sub-branch Banking Dept.

Bank Address: 1st Floor, Tower A, Gateway, No.18 Xiaguangli, North Road, East Third Ring, Chaoyang District, Beijing, 100027, P.R.China

Payee: DIA (Beijing) Healthcare Information Consulting Limited

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 _____

* Only following cards are accepted:

Foreign Credit Card: VISA & MasterCard.

Domestic Credit Card: Bank of China, China Construction Bank, Industrial and Commercial Bank of China, Guangdong Development Bank, China Industrial Bank, Huaxia Bank & China Merchants Bank Tele-banking.

For more details, please contact DIA China office.

CONTACT INFORMATION

For general inquiries and registration, contact Mr. Fei XIE at fei.xie@diachina.org

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: Industry Government University CRO/CSO Hospital/Medical Practice Independent Consultant Other

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. provides meeting services for DIA China

1. 会员信息

姓名	手机	性别: <input type="checkbox"/> 男 <input type="checkbox"/> 女
单位名称	学位	
职位	部门	
邮寄地址		<input type="checkbox"/> 工作地址 <input type="checkbox"/> 家庭地址
邮编	国家	省
电子邮件	电话	城市
		传真

2. 付款方式

会员年费: 人民币 880 元

<input type="checkbox"/> 信用卡支付	信用卡类型: <input type="checkbox"/> 境内信用卡* <input type="checkbox"/> 境外Visa 维萨卡 <input type="checkbox"/> 境外Master 万事达 * 中国银行, 建设银行, 工商银行, 广发银行, 兴业银行, 华夏银行, 招行电话银行	持卡人姓名 _____ 卡号 _____ 安全码 _____ 有效期 _____ 签名 _____
<input type="checkbox"/> 银行电汇	收款人: 科伦管理咨询(北京)有限公司 账号: 325956011898 开户行名称: 中国银行北京建国门外支行 开户行地址: 中国北京建国门外大街24号	
<input type="checkbox"/> 发票	若需发票, 请电邮: dia@diachina.org 或传真至: +86 10 5923 1090 发票和会员信息将在付款收到后邮寄给会员。	

3. 从事本行业时间 (请选择一项)

<input type="checkbox"/> 2年以下	<input type="checkbox"/> 2-5年	<input type="checkbox"/> 6-10年	<input type="checkbox"/> 11-15年
<input type="checkbox"/> 16-20年	<input type="checkbox"/> 20年以上		

4. 工作单位类别

<input type="checkbox"/> 药厂	<input type="checkbox"/> 政府部门	<input type="checkbox"/> 科研院校	<input type="checkbox"/> 实验室/CRO/CSO
<input type="checkbox"/> 医疗机构 - 医院/诊所	<input type="checkbox"/> 咨询公司	<input type="checkbox"/> 其它	

5. DIA 中国办事处联系方式:

- 地址: 中国北京市朝阳区东三环北路霞光里 18 号佳程广场 A 座 11 层 1155 室, 邮编 100027
- 邮箱: dia@diachina.org
- 传真: + 86 10 5923 1090
- 电话: + 86 10 5923 1109

DIA 主页: www.diahome.org

备注:

- 1) 科伦管理咨询(北京)有限公司代理 DIA 中国区会员服务。
- 2) 会员费一旦支付将不予退还。

DIA Membership Application Form



1. MEMBER INFORMATION

Last Name		Mobile	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
First Name		Degree	
Organization		Job Function/Department	
Job Position		Professional Title	
Mailing Address			<input type="checkbox"/> Business Address <input type="checkbox"/> Home Address
Zip	Country	Province	City
E-mail		Phone	Fax

2. PAYMENT METHODS

ANNUAL MEMBERSHIP FEE: RMB 880

<input type="checkbox"/> Credit Card	Card type: <input type="checkbox"/> Domestic Credit Card* <input type="checkbox"/> International Visa <input type="checkbox"/> International Master * Bank of China, China Construction Bank, Industrial and Commercial Bank of China, Guangdong Development Bank, China Industrial Bank, Huaxia Bank, China Merchants Tele- Banking	Cardholder Name _____ Card # _____ Security Code _____ Expiry Date _____ Signature _____
<input type="checkbox"/> Bank Transfer	Payee: Kellen Management and Consulting (Beijing) LTD. Bank Account: 325956011898 Bank Name: Bank of China, Beijing Jianguomenwai Sub-branch Bank Address: 24Jianguomenwai Street Beijing, 10004, China	
<input type="checkbox"/> Request Invoice	Email or fax the request to dia@diachina.org ; fax: +86 10 5923 1090 Once payment is received, the invoice and the membership information will be mailed to the member.	

3. YEARS OF WORKING EXPERIENCE (Please select one)

<input type="checkbox"/> <2 years	<input type="checkbox"/> 2-5 years	<input type="checkbox"/> 6-10 years	<input type="checkbox"/> 11-15 years
<input type="checkbox"/> 16-20 years	<input type="checkbox"/> > 20 years		

4. ORGANIZATION TYPE

<input type="checkbox"/> Industry	<input type="checkbox"/> Government	<input type="checkbox"/> University	<input type="checkbox"/> CRO/CSO
<input type="checkbox"/> Hospital/Medical Practice	<input type="checkbox"/> Independent Consultant	<input type="checkbox"/> Other	

5. DIA CHINA CONTACT INFORMATION

<input type="checkbox"/> Address: Room 1155, Block A, Gateway Plaza, No. 18 XiaGuangLi, North Road East 3rd Ring, ChaoYang District, Beijing, 100027, China <input type="checkbox"/> E-mail: dia@diachina.org <input type="checkbox"/> Fax: + 86 10 5923 1090 <input type="checkbox"/> Telephone: + 86 10 5923 1109

DIA Website: www.diahome.org

Notes:

- 1) Kellen Management and Consulting (Beijing) Co., Ltd., a Service Provider for DIA China.
- 2) Membership is not refundable or transferable.

Invoice Request 发票需求

Payer (individual) 付款单位 (个人)			
Service item 服务项目	Meeting Fee <input type="checkbox"/> <input type="checkbox"/> 会议费	Training Fee <input type="checkbox"/> <input type="checkbox"/> 培训费	
Amount charged 金额	RMB		
Recipient Address 收件人地址			
Recipient 收件人			
Phone 联系电话			
Participants information Note: please list all participants' names, payment method and amount. After we confirmed payment, we will make invoice and send to you. Kindly ensure your handwriting is clear and readable. Many thanks! 参会者信息 注意：您需要详细列出参会者姓名，付款方式和付款金额。我们会在款项入账并确认无误后，开具发票并邮寄给您。 请确保您的字迹清晰可辨。非常感谢！			

Kellen Management and Consulting (Beijing) Co., Ltd.

Provides meeting services for DIA China.

酒店预订表 **Hotel Booking**

截止日期Deadline Date:

2011年10月21日 **OCTOBER 21, 2011**

请回传至Please return form to

+86 21 64845699, 64845595

或发送邮件至Or email to: xieb@secec.com



光大国际大酒店（挂牌4星）

★★★★

Shanghai Everbright Convention & Exhibition International Hotel

地址：上海市漕宝路66号

Address: No.66, Caobao Road, Xuhui District, Shanghai 200235, China

电话：+86 21 64842500

Phone: +86 21 64842500

房价（含服务费、早餐）：

Room Rate: CNY 450 Per Night, Service Charge & Breakfast(s) included.

序号 No.	姓名 Name	入住日期（月/日） Check In Date (MM--DD)	离店日期（月/日） Check Out Date (MM--DD)	房型Room Type (大床/双床) (King size / Twin size)
	Mr / Ms			

联系人：_____ 移动电话：_____

Contact Person: _____ Mobile Phone: _____

特殊要求（如：到店时间、是否无烟房）：

Special Request (i.e. Arrival Time, Non-Smoking Room):

如需书面确认，请提供以下信息（两者选一即可）：

If room confirmation is needed in written form, please fill in the blanks below:

传真：_____ 电子邮箱：_____

Fax: _____ Email Address: _____

客人签名：_____

Signature: _____