

Clinical Project Management



February 24-26, 2011
Beijing Jade Palace Hotel | Beijing, China

As clinical trials become more complex and there is increasing demand for efficiency and cost-effectiveness, the knowledge and skills required to manage all aspects of a clinical project are critical. The needs in China are even greater, as there are little professional clinical project management training courses available in the market.

This training course will provide a comprehensive foundation in clinical project management, including detailed knowledge of project management practices and the skills and tools that will make the difference between a successful clinical trial and one that does not meet its goals.

WHAT YOU WILL LEARN

- ▶ Defining clinical project management
- ▶ Defining the clinical project scope
- ▶ Planning the work
- ▶ Estimating study enrollment
- ▶ Producing the schedule
- ▶ Determining the project staffing plan
- ▶ Clinical project risk management
- ▶ Clinical contracts
- ▶ Preparing an investigator budget
- ▶ Preparing a clinical trial budget
- ▶ Execution and control
- ▶ Closing the project
- ▶ Clinical project operations plan

LEARNING OBJECTIVES

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

- Demonstrate the value of clinical project management
- Apply project management best practices to clinical trials
- Understand and manage the challenges of clinical trials
- Develop accurate clinical trial timelines and budgets

**Enrollment limited to 70 registrants.
Register Early!**

WHO SHOULD ATTEND

- ▶ Clinical Project Managers, Leaders and Directors
- ▶ Clinical Trial/Study/Research/ Operations Managers and Directors
- ▶ Senior Clinical Research Associates
- ▶ Medical Affairs Professionals and Medical Directors
- ▶ Regulatory Affairs Professionals
- ▶ R&D Scientists

PROGRAM CHAIRPERSON

QingAn JIAO, MD, MSc

Head of Clinical Operations, Asia Pacific Roche Product Development in Asia Pacific (PDY)

PROGRAM COMMITTEE

Ning XU, MD, MBA

Senior Director, Head of Clinical Development Services
Covance China

Paul DAI, MD

Director, Clinical Development
Beijing Novartis Pharma Co., Ltd.

MAIN INSTRUCTOR

Cris M. HOWARD, MBA, MEd, PMP

Senior Clinical Project Manager
Product Development-Gaithersburg MD
Emergent BioSolutions

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organization they represent, or that of the Drug Information Association. Speakers and agenda are subject to change without notice. Recording of any DIA training material in any type of media, is prohibited without prior written consent from DIA.

For general inquiries and registration, contact **Mr. Fei XIE** at dia@diachina.org



DIA China, 11F/1155, Block A, Gateway Plaza, No. 18 XiGuangLi, North Road, East Third Ring, ChaoYang District
Beijing, 100027, China, Tel. +86.10.5923.1109, Fax. +86.10.5923.1090, Beijing, China. www.diachina.org, dia@diahome.org



QingAn JIAO, MD, MSc

Dr. QingAn JIAO is currently Head of Clinical Operations, Asia-Pacific, at Roche Product Development. He has more than 20 years of experience in medical research and drug development, mostly in the area of clinical research, and is very experienced in managing clinical trials in China and Asia-Pacific. Prior to joining Roche, he was the Director of the Greater China Clinical Research Unit at sanofi-aventis. Prior to that, he was the Head of Clinical Operations, Asia Pacific at MDS Pharma Services, a leading global CRO. He spent almost 10 years at Pfizer with growing responsibilities, and with extensive training and management experience in clinical research. He received his medical degree in 1986 and a further Master's degree in immunology in 1989. He has spoken at various international and national conferences and seminars on topics of clinical research and R&D activities, and was one of the members of the DIA Provisional Advisory Council of China (pACC).



Ning XU, MD, MBA

Dr. Ning XU is currently the Executive Director, Head of Clinical Development Service, Covance China. Dr. XU has many years of experience in clinical research both in pharmaceutical and CRO industries. He has worked for pharmaceutical companies such as J&J and GSK as Medical Director as well as CROs such as Excel PharmaStudies as Executive Vice President and PAREXEL in the US as a senior CRA.

Dr. XU received his MD from Peking Union Medical College in 1991. As a pulmonary physician he worked in Beijing Union Hospital for 6 years, and then he completed his postdoctoral fellowship in the Medical School, University of Illinois at Chicago, investigating on neutrophil inhibitory factor in preventing acute lung injury. He received his MBA from the University of Illinois at Chicago in 2000. He is now a board member of DIA China.



Paul DAI, MD

Dr. Paul DAI is currently working for Novartis as Director, Clinical Development, responsible for clinical operation activities in Northeast Asia region (Greater China, Taiwan and Korea). He has been working in the pharmaceutical industry for almost 15 years with big pharma companies like Novartis, Eli Lilly and GSK. He graduated from the medical school of Peking University and then became cardiologist in Beijing Cardiovascular and Lung Disease Research Center and

Beijing Anzhen Hospital. He became deeply involved in clinical development and medical affairs in a variety of therapeutic areas including CVS, neuroscience, Hepatitis B, diabetes, respiratory, oncology and anti-infectious diseases in China. Dr. DAI has participated in many scientific conferences as speaker/panelist.



Cris M. HOWARD, MBA, Med, PMP

Applying 20 years of experience in health care and biopharmaceutical drug development, Cris Howard is an expert at managing all phases of the product development lifecycle.

Currently, Cris is a Senior Clinical Project Manager at Emergent BioSolutions, a Gaithersburg, Maryland biopharmaceutical company, where she oversees the clinical trials for the government-funded anthrax vaccine and immune globulin portfolio. Cris received the Achievement Award for her above and beyond performance leading to exceeded enrollment timelines.

Prior to joining Emergent BioSolutions, Cris managed clinical trials for GlaxoSmithKline, Johnson & Johnson and Biosynexus Incorporated. Cris' more noteworthy projects include the management obesity and diabetes clinical trials

encompassing 41 countries, 48 languages, 650 clinics and over 10,000 subjects. Her innovative strategies used to attract and retain subjects earned her team the Johnson & Johnson Chairman's Award, the highest honor awarded at the company.

Cris has taught multiple continuing education courses on project management, project budgeting and subject recruitment strategies for DIA, Pharmaceutical Education and Research Institute (PERI), Cambridge Healthtech Institute (CHI), Regulatory Affairs Professionals Society (RAPS), Sociedade Brasileira de Medicina Farmaceutica (SBMF), and Argentinean Pharmaceutical Medicine Society (SAMEFA). Formerly, Cris served as practitioner faculty for the MBA Fellows program at the Johns Hopkins University Carey Business School and continues to serve as an expert reviewer for student presentations.

A Phi Beta Kappa, Cris earned her Project Management Professional (PMP) certificate from the Project Management Institute, a Certificate in Clinical Research from the National Institutes of Health, a Masters degree in Business Administration from Ohio University, a Masters degree in Health Education from The University of Texas at Austin, and a Bachelors degree in Industrial Psychology from Rhodes College.

AGENDA - DAY 1 (Thursday, Feb 24, 2011)

8:30 – 9:00 AM WELCOME AND INTRODUCTIONS

- Welcome
- Introductions
- Course Objectives

9:00 – 9:45 AM MODULE 1: WHY CLINICAL PROJECT MANAGEMENT?

- The Challenges of product development
- Why project management?

9:45 – 10:45 AM MODULE 2: WHAT IS CLINICAL PROJECT MANAGEMENT?

- SMALL GROUP EXERCISE: Best (and worst) project managers
- History of project management

- Key definitions
- Characteristics of a successful project manager
- SELF ASSESSMENT: Characteristics of a successful project manager

10:45 – 11:00 AM REFRESHMENT BREAK

11:00 AM-12:00 PM MODULE 3: DEFINING THE CLINICAL PROJECT SCOPE

- Strategic vision & objectives
- Scope statements
- Fonton-a-Yuth LV4-EVR-003 clinical protocol outline
- SMALL GROUP EXERCISE: Fonton-a-Yuth LV4-EVR-003 scope statement
- INDEPENDENT EXERCISE: Clinical project scope statement

12:00 – 1:00 PM LUNCH

1:00 – 3:00 PM MODULE 4: PLANNING THE WORK

- Breaking down the work: Sub-projects, work packages & deliverables
- Work package list & descriptors
- Work package durations
- GROUP EXERCISE: Credit card estimate
- Creating a network map

3:00 – 3:15 PM REFRESHMENT BREAK**3:15 – 4:15 PM MODULE 4: PLANNING THE WORK (CONTINUED)**

- SMALL GROUP EXERCISES: Post-it Note Exercise

4:15 – 4:30 PM DAY 1 REVIEW, CHECK-IN, & 'HOMEWORK'**AGENDA - DAY 2 (Friday, Feb 25, 2011)****8:30 – 9:00 AM DAY 1 REVIEW**

- Homework discussion

9:00 – 9:45 AM MODULE 5: ESTIMATING ENROLLMENT

- Estimating enrollment
- SMALL GROUP EXERCISE: Fonton-a-Yuth LV4-EVR-003 enrollment factors

9:45 AM – 12:00 PM MODULE 6: PRODUCING THE SCHEDULE

(Includes a 15 minute refreshment break)

- Producing the schedule: Gantt charts
- Balancing the schedule: Critical path compression and managing float
- SMALL GROUP EXERCISE

12:00 – 1:00 PM BREAK FOR LUNCH**1:00 – 2:30 PM MODULE 7: DETERMINING THE PROJECT STAFFING PLAN**

- High performance teams
- Resource allocation
- Resource analysis
- High performance team charter
- SMALL GROUP EXERCISES

2:30 – 2:45 PM REFRESHMENT BREAK**2:45 – 4:15 PM MODULE 8: CLINICAL PROJECT RISK MANAGEMENT**

- Trends in clinical project risk management
- Risk assessment
- Risk control
- SMALL GROUP EXERCISE

4:15 – 4:30 PM DAY 2 REVIEW, CHECK-IN, & 'HOMEWORK'**AGENDA - DAY 3 (Saturday, Feb 26, 2011)****8:30 – 9:00 AM DAY 1 & 2 REVIEW**

- Homework review

9:00 – 10:30 AM MODULE 9: PREPARING AN INVESTIGATOR BUDGET

- Estimating costs per subject
- Estimating screen fail costs
- Estimating early withdrawal costs
- Estimating fixed investigator costs
- PRACTICAL EXERCISE

10:30 – 10:45 AM REFRESHMENT BREAK**10:45 AM-12:00 PM MODULE 10: PREPARING A CLINICAL TRIAL BUDGET**

- A few words about clinical trial budgeting
- Clinical trial budgets
- PRACTICAL EXERCISE #1: Estimating CRO costs
- PRACTICAL EXERCISE #2: Estimating consulting fees
- Budgeting tips and tricks

12:00 – 1:00 PM BREAK FOR LUNCH**1:00 – 3:00 PM MODULE 11: CLINICAL TRIAL EXECUTION, MONITORING AND CONTROL**

- Clinical trial execution
- Clinical trial monitoring and control
- Clinical trial score cards
- GROUP EXERCISE: What would you do if

3:00 – 3:15 PM REFRESHMENT BREAK**3:15 – 4:00 PM MODULE 12: CLINICAL TRIAL CLOSE-OUT**

- Go / no-go analysis
- Termination
- Team closure
- Lessons learned

4:00 – 4:30 PM WRAP-UP

- RE-VISIT: Course objectives
- Summary of lessons learned
- Course evaluation

4:30 PM ADJOURN

Clinical Project Management Training Course

Meeting I.D. # 11982 – February 24-26, 2011

Beijing Jade Palace Hotel, Beijing, CHINA

LOCATION AND VENUE

Beijing Jade Palace Hotel, 76 ZhiChun Road, Haidian District, Beijing, P.R. China. The closest airport to this hotel is Beijing International Airport.

CONTACT INFORMATION

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

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 FEBRUARY 17, 2011

Cancellations must be made in writing and received by February 17, 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
22 November-20 February 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.

Industry Early-bird* (22 November-16 January)

Industry Standard (17 January-20 February)

Industry Onsite (21 February-24 February)

* **Early Bird Closes 16 January 2011**

	NONMEMBER	MEMBER
Industry Early-bird* (22 November-16 January)	RMB 5380 <input type="checkbox"/>	RMB 4500 <input type="checkbox"/>
Industry Standard (17 January-20 February)	RMB 5880 <input type="checkbox"/>	RMB 5000 <input type="checkbox"/>
Industry Onsite (21 February-24 February)	RMB 6380 <input type="checkbox"/>	RMB 5500 <input type="checkbox"/>
		MEMBERSHIP
		RMB 880 <input type="checkbox"/>

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

Discount Fees

Academia / Government (Full-time)

	NONMEMBER	MEMBER
Academia / Government (Full-time)	RMB 4130 <input type="checkbox"/>	RMB 3250 <input type="checkbox"/>

***WHEN PAYMENT IS MADE BY BANK WIRE, PLEASE NOTE THAT YOUR PAYMENT MUST BE RECEIVED PRIOR TO 21 FEBRUARY, 2011. IF YOU CHOOSE EARLY-BIRD PRICE, YOU MUST RECEIVE PRIOR TO 16 JANUARY, 2011.**

***AFTER 20 FEBRUARY 2011 ONLY ONSITE REGISTRATION WILL BE 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.

* 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. #11982

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:

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Card # _____ Security Code _____

Visa Master Card Domestic Credit Card

Signature _____

* Kindly note that only following cards are currently 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.

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.

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临床项目管理培训班



2011年2月24-26日

中国·北京·北京翠宫饭店

仅限**70**人参会
报名从速!

内容概览

随着临床试验复杂性的加深及对临床试验效率与成本效益需求的不断增长，临床项目管理方面所需的知识和技能更凸显其重要性。目前中国市场上针对临床项目的专业培训课程相对缺乏，因此对培训的需求也更大。

本次课程将为临床项目管理提供一次系统和全面性的培训，包括详细具体的项目管理实践知识、技能、方式方法，以及这些知识和技能对临床试验的成功与否所具有的影响。

参会人员

- ▶ 临床项目负责人、领导者及总监
- ▶ 临床试验/学习/研究/运作负责人
- ▶ 高级临床研究员
- ▶ 医务专业人员及医学部主要负责人
- ▶ 法规事务专业人员
- ▶ 研发工作者

学习内容

- ▶ 临床项目管理的定义
- ▶ 确定临床项目的范围
- ▶ 工作事项的规划
- ▶ 试验参与人数的评估
- ▶ 试验日程的制定
- ▶ 项目人员的确定与安排
- ▶ 临床项目的风险管理
- ▶ 临床合约
- ▶ 临床研究者的财务预算
- ▶ 临床试验项目的财务预算
- ▶ 实施与监控
- ▶ 关闭项目
- ▶ 临床项目的运作计划

学习目的

在培训班结束时，与会者应能够：

- 阐释临床项目管理的价值
- 将项目管理最佳实践应用到临床试验中
- 理解并管理临床试验所应对的难题和挑战
- 制定精确的临床试验进程时间表和预算

组织委员会主席

焦庆安 医学博士
亚太区临床运营负责人
罗氏亚太区临床研发中心

组织委员会

徐宁 医学博士
执行总监、临床研究部中国区负责人
科文斯中国

戴欣 医学博士
临床研发总监
北京诺华制药有限公司

主讲人

Cris M. HOWARD 工商管理硕士
产品开发部高级临床项目负责人
Emergent BioSolutions公司

除非特别说明，讲者的观点并不代表其组织或DIA的观点。讲者及日程如有更改，恕不另行通知。除非预先获得DIA书面同意，不得以任何形式录制本次会议及资料。

会议咨询：请与 谢飞先生 联系

电话：+86 10 5923 1109
传真：+86 10 5923 1090
E-mail: dia@diachina.org



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, 网址: www.diachina.org, 邮件: dia@diahome.org



焦庆安博士目前就任罗氏亚太临床研发中心亚太区临床运营负责人。他在医学研究与药物开发领域拥有20多年的经验，尤其是在临床研究领域，在中国和亚太区临床试验管理方面经验非常丰富。在加入罗氏之前，焦庆安博士在赛诺菲安万特研发中心任大中华区临床研究总监一职。此前，他在全球领先的CRO—美迪生药业研究有限公司任亚太区临床运营总监一职。焦庆安博士在辉瑞工作了近10年，这10年间，他在临床研究方面积累了丰富的培训和管理经验，职位也不断得到提升。他于1986年获得医学学位，1989年获得免疫学硕士学位。焦庆安博士经常在各种国内外会议及研讨会上做关于临床研究与研发活动的主题演讲，曾是DIA中国区临时顾问委员会成员。



徐宁博士目前就任科文斯执行总监，临床研究部中国区负责人。徐宁博士在制药企业及临床研究机构拥有多年丰富的经验。他曾在制药企业如强生公司及葛兰素史克公司任职医学总监，在合同研究组织如依格斯特任执行副总裁，在美国PAREXEL公司任职高级临床研究专员。

徐宁博士1991年获得北京协和医科大学博士学位。他曾在北京协和医院做了6年肺科医师，之后在芝加哥伊利诺伊大学医学院完成博士后研究工作，主要研究在预防急性肺损伤中性粒细胞抑制因子的作用。徐宁博士于2000年获得芝加哥伊利诺伊大学工商管理硕士学位，现为DIA中国区董事会成员。



戴欣博士目前就任北京诺华制药有限公司临床研发总监，主要负责东北亚地区（大中国区、台湾及韩国）的临床运营。他在医药行业有近15年的工作经验，先后在一些大的制药公司如诺华、礼来制药公司和葛兰素史克公司任职。他毕业于北京大学医学院，之后成为北京心血管和肺疾病研究中心和北京安贞医院的心脏科医生。他深入参与中国多种治疗领域的临床开发及医学事务，包括心血管、神经系统、乙型肝炎、糖尿病、呼吸疾病、肿瘤及抗感染疾病等。戴欣博士经常在各种学术会议上做演讲。



Cris HOWARD在医疗保健及生物制药开发领域拥有20年丰富的工作经验，尤其擅长于产品开发各个阶段的项目管理运营。

Cris目前任Emergent BioSolutions公司高级临床项目负责人。Emergent BioSolutions公司是一家位于美国马里兰州盖瑟斯堡的生物制药公司，Cris在该公司主要负责的项目是对由政府出资的炭疽疫苗和免疫球蛋白组合临床试验进行监督和管理。Cris以其卓越表现获得了杰出成就奖。

在加入Emergent BioSolutions公司之前，Cris曾在葛兰素史克公司、强生公司及Biosynexus公司负责临床试验的管理工作。Cris所参与负责领导的肥胖和糖尿病临床试验的管理项目涵盖了41个国家，48种语言，650个诊所及10000多个学科。这些用于吸引和保留学科的创新策略为她的团队赢得了强生公司最高荣誉奖—主席奖。

作为世界知名的生物制药领域专家，Cris还为药物信息协会（DIA）、药学教育研究院（PERI）、剑桥健康技术研究所（CHI）、法规事务专业协会（RAPS）、巴西医药学会（SBMF）和阿根廷制药医学会（SAMEFA）教授多个有关项目管理的课程，包括继续教育课程、项目预算及受试者招募策略等课程。此前，Cris在约翰霍普金斯大学凯瑞商学院任职MBA学员教程从业讲师，并为学生报告做专家评审。

Cris拥有项目管理协会PMP认证；美国国立卫生研究院的临床研究认证；俄亥俄大学工商管理硕士学位；德州大学奥斯汀分校健康教育硕士学位；及罗德学院工业心理学学士学位。

日程 - 第一天 (2月24日, 星期四)

8:30 - 9:00 欢迎致辞及介绍

- 欢迎致辞
- 介绍
- 课程目标

9:00 - 9:45 模块1: 为什么进行临床项目管理?

- 产品开发面临的挑战
- 为什么需要项目管理?

9:45 - 10:45 模块2: 什么是临床项目管理?

- 小组练习: 最佳(最差)项目负责人
- 项目的历史
- 主要定义
- 一个成功项目负责人的特点
- 自我评估: 一个成功项目负责人的特点

10:45 - 11:00 茶歇

11:00 - 12:00 模块3: 确定临床项目的范围

- 战略远景及目标
- 范围说明
- Fonton-a-Yuth LV4-EVR-003 临床方案大纲
- SMALL GROUP EXERCISE: Fonton-a-Yuth LV4-EVR-003 范围说明
- 独立练习: 临床项目范围说明

12:00 - 13:00 午餐

13:00 - 15:00 模块4: 工作事项的规划

- 工作分解: 分类项目, 具体工作及应交付的项目结果
- 工作列表及概述
- 工作周期
- 分组练习: 信用卡估算
- 建立工作的互联网

15:00 - 15:15 茶歇

15:15 - 16:15 模块4: 工作事项的规划 (续)

- 小组练习: 记事贴注释练习

16:15 - 16:30 第一天活动的回顾、确认及“课后作业”

日程 - 第二天 (2月25日, 星期五)

8:30 - 9:00 第一天回顾

- 作业讨论

9:00 - 9:45 模块5: 参与人数的评估

- 参与人数的评估
- 小组练习: Fonton-a-Yuth LV4-EVR-003人员因素

9:45 - 12:00 模块6: 试验进度表的制定

(包括15分钟茶歇)

- 制定试验进度表: 甘特图
- 进度表安排: 关键路径的压缩及浮动方面的管理
- 小组练习

12:00 - 13:00 午餐

13:00 - 14:30 模块7: 项目人员的确定与安排

- 高绩效团队
- 资源分配
- 资源分析
- 高绩效团队章程
- 小组练习

14:30 - 14:45 茶歇

14:45 - 16:15 模块8: 临床项目的风险管理

- 临床项目风险管理趋势
- 风险评估
- 风险控制
- 小组练习

16:15 - 16:30 第二天活动的回顾、确认及“课后作业”

日程 - 第三天 (2月26日, 星期六)

8:30 - 9:00 第一天及第二天回顾

- 复习课后作业

9:00 - 10:30 模块9: 临床研究者的成本预算

- 参与试验者的费用估算
- 审察不理想试验的费用估算
- 提前退出/终止试验的费用估算
- 固定的研究者的费用估算
- 实例练习

10:30 - 10:45 茶歇

10:45 - 12:00 模块10: 临床试验项目的财务预算

- 临床试验预算概述
- 临床试验预算
- 实例练习#1: CRO使用外包服务的费用估算
- 实例练习#2: 咨询费用估算
- 处理预算的方法与技巧

12:00 - 13:00 午餐

13:00 - 15:00 模块11: 临床试验的实施、监测与控制

- 临床试验的实施
- 临床试验的监控
- 临床试验评分卡
- 分组练习: 如果...你会怎么做

15:00 - 15:15 茶歇

15:15 - 16:00 模块12: 终止临床试验

- 继续/终止的分析判断
- 终止临床试验
- 停散项目团队
- 总结经验教训

16:00 - 16:30 总结

- 回顾: 课程目标
- 经验教训总结
- 课程评估

16:30 会议结束

临床项目管理培训班
会议编码: #11982 • 2011年2月24-26日
中国 • 北京 • 北京翠宫饭店

会议举办场所:

北京翠宫饭店
北京市海淀区知春路76号
Tel: +86 10 62628888-55090
Fax: +86 10 62561447

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: dia@diachina.org

取消注册: 须在2011年2月17日前(含2月17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2月17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2月17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2月20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 (11月22日-01月16日)	RMB5380 <input type="checkbox"/>	RMB4500 <input type="checkbox"/>
标准价格 (01月17日-02月20日)	RMB5880 <input type="checkbox"/>	RMB5000 <input type="checkbox"/>
现场注册 (02月21日-02月24日)	RMB6380 <input type="checkbox"/>	RMB5500 <input type="checkbox"/>

* 提前注册价格优惠截止至2011年1月16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)	RMB4130 <input type="checkbox"/>	RMB3250 <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1月16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2月21日前收到您的注册费用。

* 2011年2月20日后只接受现场注册。

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。

* 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 #11982

银行帐号: 803020296408091001

开户行: 中国银行北京建国门外支行

银行地址: 北京市朝阳区建国门外大街24号

收款人: 科伦管理咨询(北京)有限公司

SWIFT : BKCH CN BJ 110

(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 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

更多注意事项, 请联络DIA中国办公室

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)有限公司为DIA中国提供会议服务

临床项目管理培训班

DIA Clinical Project Management Training Course



北京市海淀区知春路 76 号

76.ZhiChun Road, HaiDian District ,BeiJing, P.R
CHINA 100086

Internet: <http://www.jadepalace.com.cn>

Tel:010-62628888-55090, Fax:010-62561447

客房预订表格

ROOM RESERVATION FORM

客房预订邮箱: jpsales@163.com

Room Reservation E-mail: jpsales@163.com (English reservation)

(All reservations must be made before Feb.18, 2011)

姓名 Name:

(First)

(Middle)

(Last)

联系电话及传真 Phone/Fax Numbers: Phone:

Fax: _____

邮箱地址 E-mail Address:

到店日期 Arrival Day/Date:

离店日期 Departure Day/Date:

可吸烟房或无烟房 Requests: Smoking or non-smoking: _____

Due to limited smoking rooms requests will be taken on a first case basis

标准间 (500 元/间夜) Number of Standard Room (500RMB/per night) : _____ 间

豪华间 (600 元/间夜) Number of Deluxe Room (600RMB/per night): _____ 间

*以上价格包含单份早餐、游泳健身、上网和 15%服务费 (如需单加早餐 50 元/份)。

Above cost including breakfast (All rooms include one or two breakfast. RMB 50 will be charged as extra breakfast fee), fitness center, swimming and 15%service charge.

*酒店接受信用卡结账: 牡丹卡、龙卡、金穗卡、长城卡、VISA、AE、JBC、DINERS CLUB.

Credit cards are accepted: Peony, Dragon, Golden Harvest card, Great Wall Card, VISA, AE, JBC, DINERS CLUB.

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



1. MEMBER CONTACT INFORMATION 会员信息

Date 日期: _____

Last Name姓	First Name名	Mobile手机	Sex性别: <input type="checkbox"/> Male男 <input type="checkbox"/> Female女
Company 公司名称 _____			
Job Position职位 _____		Degrees Held学历 _____	Professional Title职称 _____
<input type="checkbox"/> Business Address工作地址	<input type="checkbox"/> 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

<input type="checkbox"/> 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
<input type="checkbox"/> Credit Card 信用卡类型	<input type="checkbox"/> Amex 美国运通卡 <input type="checkbox"/> Visa 维萨卡 <input type="checkbox"/> Master 万事达卡 Exp. Date有效期至 _____
Card# 卡号 _____	Signature签名 _____
<input type="checkbox"/> 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: 803020296408091001 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
<input type="checkbox"/> 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。

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

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 |
|---|---|--|---|---|
| <input type="checkbox"/> Pharmaceuticals 制药 | <input type="checkbox"/> Regulatory 法规 | <input type="checkbox"/> CRO / CSO / MSO | <input type="checkbox"/> University / College 大学/学院 | <input type="checkbox"/> Hospital 医院 |
| <input type="checkbox"/> Devices 器械 | <input type="checkbox"/> Health Agency 卫生管理机构 | <input type="checkbox"/> Marketing / Advertising 市场/广告 | <input type="checkbox"/> Academic Health Center 医学中心 | <input type="checkbox"/> MCO / HMO |
| <input type="checkbox"/> Biotechnology 生物技术 | <input type="checkbox"/> Other 其它 | <input type="checkbox"/> Independent Consultant 独立咨询人员 | <input type="checkbox"/> Technical Training School 技术培训中心 | <input type="checkbox"/> Primary Care 开业医生/诊所 |
| <input type="checkbox"/> Other 其它 | | <input type="checkbox"/> Staffing / Personnel 职员/人员 | <input type="checkbox"/> Full Time Student 全日制学生 | <input type="checkbox"/> Other 其它 |
| | | <input type="checkbox"/> Information Technology 信息技术 | <input type="checkbox"/> Other 其它 | |
| | | <input type="checkbox"/> 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 51 - 500 employees 501 - 5,000 employees 5,001 - 15,000 employees
1 - 50 名员工 51 - 500 名员工 501 - 5,000 名员工 5,001 - 15,000 名员工
 15,001 - 50,000 employees More than 50,001 employees
15,001 - 50,000 名员工 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

Mail 邮寄: Rm. 1177, Block A, Gateway Plaza, No. 18 XiaGuangLi, North Road East 3rd Ring, ChaoYang District, Beijing, 100027, China

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1177室, 100027

E-mail 电邮: dia@diachina.org

Fax 传真: + 86 10 5923 1090

Online 在线方式请登陆: <http://www.diahome.org>

Tel: + 86 10 5923 1109

Fax: + 86 10 5923 1090



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