DIA 2017 中国

临床试验项目管理研讨班

第六期 | 中高级班

6th Clinical Project Management Workshop
Intermediate to Advanced

3月29-31日 | 上海齐鲁万怡大酒店

March 29-31
Courtyard by Marriott Shanghai Pudong

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2017

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DIA 中国

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艾滋病营养网络以及公共健康政策委员会总裁兼首席执行官，C3综合临床顾问，执行理事
美国药学会流行病学部
心理健康委员会联席主席
国际政策联合委员会流行病团体干事

本课程为药物临床研发机构和单位中从事临床项目管理的经理、高级经理和总监所设计。课程以实践为基础，重点培养参会者实际操作技能和案例分析能力，通过学习参会者将深入理解并掌握临床项目管理所需的工作实践知识和项目管理技能。本课程将帮助参会者理解、建立并执行临床试验计划，评估并修改申 办者的提案；理解，建立并执行风险识别和风险规避策略。培训将涵盖从计划制定，计划完善，项目执行到项目关闭等临床项目管理中的不同阶段。

学习内容

- 临床项目管理的定义
- 确立和明确定义临床项目的范畴
- 根据风险规避和规划质量原则制定工作计划
- 评估全球临床研究的入组和推动招募工作
- 制定全球临床试验规划和意外应急计划
- 用微软的项目管理软件制作项目工作分解结构和时间进度表
- 如何与高绩效的全球团队合作
- 预估并管理国际多中心临床试验预算
- 制定，执行并管控全球临床项目运营计划
- 基于风险基础的临床试验项目管理
- 按照质量设计原则，计划和实施临床项目
- 成果：制定自己的临床项目管理计划

目标听众

- 临床试验经理/高级临床试验经理
- 临床项目经理/高级临床项目经理
- 高级临床项目执行专员
- 临床运营总监/临床项目总监
- 合同/财务经理
- 临床研究外包及供应商经理和高级经理

会议网址:
https://www.eventbank.cn/event/7370/

议程

第一天 | 3月29日 • 星期三

7:30 – 8:30 **现场报到**

8:30 – 9:00 **欢迎致辞及培训介绍**

9:00 – 10:30 **模块1：复习临床项目管理概念**

- 什么是项目管理及其重要性
- 临床项目管理的周期以及各个阶段
- 床项目管理9项核心知识领域
- 临床项目管理的周期以及各个阶段
- 产品群项目，产品组合项目和单一项目管理之间的比较
- 临床项目管理理论和实际操作的区别
- 组织结构对于临床项目管理的影响
- 矩阵型组织和项目型组织结构的比较

10:30 – 10:45 **茶歇**

10:45 – 12:30 **模块1：复习临床项目管理概念（继续）**

- 一个成功项目经理的特征
- 自我评估：一个成功的项目经理的特征
- 领导力与管理
- VMOSA：愿景，使命，目标，战略和行动计划
- 在战略愿景和使命的基础上建立项目目标和实施策略
- 小组讨论：VMOSA案例分析
- 项目小组管理方法和技巧
- 通过说服和协商进行管理
- 复习：模块1的理论讨论

12:30 – 13:30 **午餐**

13:30 – 15:00 **模块2：临床项目管理范围以及时间管理**

- 临床项目管理范围：回顾
- 如何界定工作范围：子项目，工作包，工作元素
- 工作包列表和描述
- 工作包的持续时间
- 浏览：高级项目范围案例研究
- 成果：总线和分项成果
- 案例分析：招标书，计划书，工作声明(SOW)和任务

15:00 – 15:15 **茶歇**

15:15 – 17:00 **模块2：临床项目管理范围以及时间管理（继续）**

- 创建相关人员图表来估计项目时间
- 把相关人员和各项实施结果连接起来
- 设置时间表和执行计划
- 小组练习：范围，时间安排及交付案例研究

17:00 – 17:30 **第一天学习内容复习和课后作业**

第二天 | 3月30日 • 星期四

8:30 – 9:00 **第一天学习内容复习**

9:00 – 11:00 **模块3：创建时间表：基础和高级的微软的项目管理软件应用技巧**

- 制作日程草案：使用和制作GANTT图和PERT图
- 权衡计划：关键路径的压缩及管理浮动
- 小组练习：了解你的第1号项目
- 了解和利用微软的项目管理和其他项目管理软件
- 在微软的项目管理软件中建立并关联计划表
- 建立并关联日程安排：了解你的项目2号

11:00 – 11:15 **茶歇**

11:15 – 12:30 **模块3：创建时间表：基础和高级的微软的项目管理软件应用技巧（继续）**

- 小组案例分析：寻找关键路径，并确定有风险的关键行动项目
- 解决计划表中的问题：用主要业务指标（MBO）等技术识别风险
- 将项目连接到一起：SOW，WBS和项目进度
- 小组练习：圆桌项目评估

12:30 – 13:30 **午餐**

13:30 – 15:00 **模块4：临床项目成本，预算和成本管理**

- 使用SOW和TOA预估劳动力资源和人力资源成本
- 资源和人员配置的分析和所运用的工具
- 小组案例分析：了解你的第3号项目
- 预估人力资源成本：内部和外部
- 整个项目生命周期的资源分配
- 从SOW、TOA和项目计划中分解并预估成本
- 每个病人和研究机构的成本

15:00 – 15:15 **茶歇**

15:15 – 17:00 **模块4：临床项目成本，预算和成本管理（继续）**

- 人力资源成本
- 供应商和服务供应商成本
- 整合在一起：使用项目管理工具建立和评估项目预算
- 项目预算分析：使用交付时间表估算整个项目生命周期的项目支出
- 小组案例分析：了解你的第4号项目
- 项目支出的分析和方法：多样的技术

17:00 – 17:30 **第二天活动的回顾、确认及课后作业**

议程

第三天 | 3月31日 • 星期五

8:30 – 9:00　复习

- 第一天和第二天学习内容复习
- 课后作业讨论
- 小组案例分析：了解你的第5号项目

9:00 – 11:00　模块 5: 高级项目质量控制和风险管理

- 什么是质量，什么是质量控制
- 定义可接受的项目质量水准
- 基于质量的设计（quality by design）原则
- 制作和评估基于质量的设计原则
- 小组案例分析：了解你的第6号项目
- 定义和确定项目的风险
- 管理项目风险技巧和原则
- 制作和评估项目风险管理计划
- 小组练习：风险管理案例分析

11:00 – 11:15　茶歇

11:15 – 12:00　模块6：计划和启动临床试验项目

- 项目章程：它的目的，设计和重要性
- 临床试验预算
- 项目章程模板
- 项目计划：它的目的，设计和重要性
- 项目计划模板
- 完成项目计划：关键成功的项目管理
- 完整的项目计划：项目管理成功的关键
- 实战演练：创建你的项目计划
- 小组案例分析：了解你的第7号项目

12:00 – 13:00　午餐

13:00 – 15:00　模块7：临床试验的制定，执行及管控

- 临床试验的执行：每天的临床项目管理工作
- 卓越的执行：按照项目计划不是万能的
- 项目管理指标：什么，何时，何地以及如何进行
- 项目管理分析和报告技巧
- 临床试验的监督、评估和管控
- 根据管理目标：MBO战略和成果
- 小组案例分析：了解你的第8号项目

15:00 – 15:15　茶歇

15:15 – 16:30　模块8：临床项目的领导艺术

- 领导与管理
- 什么是领导？
- 领导风格和技巧
- 为你的团队增添动力
- 系统理论：大画面和小画面
- 小组案例分析：了解你的第9号项目
- 经验：以身作则

16:30 – 17:00　总结

- RE-VISIT：课程目标和核心理念
- 实践经验，技巧和建议总结
- 跟进阅读和作业[选修]
- 课程评估

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DIA CHINA

The 6th DIA China Clinical Project Management Workshop

Intermediate to Advanced Level

March 29-31, 2107 | Courtyard by Marriott Shanghai-Pudong

MAIN INSTRUCTOR

Manley R. Finch, PhD, MPH, MSc
Program Director,
Neurology WCCT Global LLC
Executive Director,
HIV Nutrition Network
Chair, Public Health Policy Committee
Co-Chair, Mental Health Committee
APHA Epidemiology Section
Past Secretary, International Joint Policy Committee - Societies of Epidemiology

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PROGRAM COMMITTEE

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Executive Vice President
Head of Clinical Development and Regulatory Affairs
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Sr. Director of Greater China, AP, Middle East and Africa, Global Clinical Development
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Qinan JIAO, MD
Sr. Director, Global Clinical Research Operation
Xian Janssen Pharmaceutical Co.,Ltd.

This is a hands-on skills based course. Where you see "Understanding your project" the attendees will be working on their own project/s they are currently assigned. The skills passed on in the course lead to the attendees being able to construct their own RFPs, proposals, SOW, TOAs, Project Plans [complete], Communication Plans, and Close Out Plans.

Learning Objective

- Demonstrate the value of project management.
- Define the characteristics of a successful project manager.
- Implement clinical project management leadership skills
- Appreciate the scope of the project.
- Produce the project schedule.
- Determine a staffing plan.
- Assess project risk and design risk mitigation plans.
- Estimate a clinical trial budget.
- Manage the clinical project from start to finish.

Target Audience

- Clinical Trail Manager / Sr. Clinical Trail Manager
- Clinical Project Manager / Sr. Clinical Project Manager
- Sr. Clinical Project Executive
- Clinical Operation Director /Clinical Project Director
- Contract/Finance Manager
- CRO & Vendor Manager/ Sr. Manager

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AGENDA | DAY 1 | March 29, Wednesday

7:30 – 8:30 **Registration**

8:30 – 9:00 **Welcome and Introduction**

- Welcome
- Introductions
- Course Objectives and Housekeeping

9:00 – 10:30 **MODULE 1: Review of Clinical Project Management Concepts**

- What is project management and why is it important?
- The life-cycle stages of a program or project
- The nine (9) PMI core project management knowledge areas
- Portfolio, program, and project management – compare and contrast
- Theoretical and contemporary approaches to project management
- Organizational structure influences program/project management.
- Matrices vs. Projectized organizational structures.

10:30 – 10:45 **Refreshment Break**

10:45 – 12:30 **MODULE 1: Continued**

- Characteristics of a successful program/project manager
- SELF ASSESSMENT: Characteristics of a successful project manager
- Leadership versus management
- VMOSA; Vision, Mission, Objectives, Strategy, Action Plans
- Strategic vision and mission create project objectives and tactics
- SMALL GROUPS CASE STUDY: VMOSA case studies
- Project team management skills and techniques
- Managing by persuasion and negotiation.
- REVIEW: AM Concepts discussion

12:30 – 13:30 **Luncheon**

13:30 – 15:00 **MODULE 2: Project Scope and Time Management**

- Defining the Project Scope: A review
- How to define the scope of work: Sub-projects, work packages, work elements
- Work package list & descriptors
- Work package durations
- EXPLORE: Advanced project scope case studies
- Deliverables: Top-line and sub deliverables
- CASE STUDY EXERCISE: RFPs, Proposals, Statement of Work (SOW) and Task Order Agreements (TOA) case studies

15:00 – 15:15 **Refreshment Break**

15:15 – 17:00 **MODULE 2: (continued)**

- Creating a network map to estimate timelines
- Connecting the network map to deliverables and sub deliverables
- Building the timelines and execution schedules
- SMALL GROUPS EXERCISES: Scope, timeline, and deliverable case studies

17:00 – 17:30 **DAY 1 REVIEW, CHECK-IN, & 'HOMEWORK'**

AGENDA | DAY 2 | March 30, Thursday

8:30 – 9:00 **DAY 1 REVIEW**

- Homework review and discussion
- Review of core concepts from Day 1
- Introduction to MS Project

9:00 – 11:00 **MODULE 3: Creating the Schedule: Basic and Advanced Work Scheduling**

- Producing the draft schedule: Using and producing GANTT and PERT charts
- Balancing the schedule: Critical path compression & managing float
- SMALL GROUPS EXERCISE: Understanding your project No. 1
- Understanding and utilizing MS Project and other PM Software
- Entering and linking the schedule in MS Project
- Entering and linking the schedule: Understanding your project No. 2

11:00 – 11:15 **Refreshment Break**

11:15 – 12:30 **MODULE 3: Creating the Schedule - Continued**

- SMALL GROUPS CASE STUDIES: Finding the critical path and identify critical action items at risk.
- Troubleshooting the schedule: Identifying risk using MBO and other techniques
- Linking it all together: SOW, WBS, Project timelines.
- SMALL GROUPS EXERCISE: Round table project assessments.

12:30 – 13:30 **Lunch**

13:30 – 15:00 **MODULE 4: Project Cost, Budgeting, and Cost Management**

- Estimating labor and staff resource requirements using SOW and TOA
- Resource and staffing analyses and tools
- SMALL GROUPS CASE STUDIES: Understanding your project No. 3
- Estimating labor costs: internal and external
- Resource allocation across the project life cycle
- Breaking down and estimating cost from the SOW, TOA, and Project Plans
- Per patient costs and Investigative site costs

15:00 – 15:15 **Refreshment Break**

15:15 – 17:00 **MODULE 4: Continued**

- Resource staffing costs
- Vendor and service provider costs
- Putting it all together: Building and assessing the project budget using PM tools, spreadsheets.
- Project budget analyses: Using deliverables and timelines to estimate project spending across the project life cycle.
- SMALL GROUPS CASE STUDIES: Understanding your project No. 4
- Project spend analytics and methodology: Various techniques

17:00 – 17:30 **DAY 2 REVIEW, CHECK-IN, & 'HOMEWORK'**

AGENDA | DAY 3 | March 31, Friday

8:30 – 9:00 **DAY 1 & 2 REVIEW**

- Review of Day 1 & 2
- Homework review and discussion
- CASE REVIEW DISCUSSION: Understanding your project No. 5

9:00 – 11:00 **MODULE 5: Advanced Project Quality and Risk Management**

- What is quality – what is project quality control
- Defining acceptable project quality standards
- Quality by Design (QbD) principles
- Crafting and assessing QbD plan
- SMALL GROUPS CASE STUDIES: Understanding your project No. 6
- Defining and identifying project risk
- Managing project risk techniques and principles
- Crafting and assessing a project risk management plan
- SMALL GROUPS EXERCISE: Review of risk management case studies

11:00 – 11:15 **Refreshment Break**

11:15 – 12:00 **Integrating the parts into a cohesive whole**
MODULE 6: Planning and Initiating the Project

- The Project Charter: its purpose, design, and importance
- Review of the Project Charter Template
- The Project Plan: its purpose, design, and importance.
- Review of the Project Plan Template
- Completing a Project Plan: Key to successful project management
- PRACTICAL EXERCISE #1: Creating your Project Plan
  - RFP, Proposals, SOW, TOA
  - WBS, Timelines and Budgets
  - Dependencies, Assumptions and Constraints
  - Communication Plan
  - Stakeholder assessments
- SMALL GROUPS CASE STUDIES: Understanding your project No. 7

12:00 – 13:00 **Lunch**

13:00 – 15:00 **MODULE 7: Clinical Trial Execution, Monitoring and Control**

- Clinical trial execution: Day to day CPM activities.
- Executing with excellence: Following the Project Plan isn't everything
- Project Management Metrics; what, when, where, and how.
- Project management analytics and reporting techniques
- Clinical trial monitoring, assessment, and control
- Managing by objectives: MBO strategies and deliverables.
- SMALL GROUPS CASE STUDIES: Understanding your project No. 8

15:00 – 15:15 **Refreshment Break**

15:15 – 16:30 **MODULE 8: Clinical Trial Leadership Skills**

- Leading versus managing
- What is a leader?
- Leadership Styles and Skills
- Empowering your team
- Systems theory: the big picture and the small picture.
- SMALL GROUPS CASE STUDIES: Leading your project No. 9
  - Managing by objectives MBO
  - Empowering your team members
  - Systems theory in practice
  - Team closure procedures: The Final Count-Down
- Lessons learned; Leading by example

16:30 – 17:00 **Wrap-up**

- RE-VISIT: Course objectives and core concepts covered
- Summary of practical lessons, tips, and advice learned
- Follow up reading and homework [elective].
- Course evaluation

讲者介绍 / About the Speakers

Manley R. Finch, PhD, DrPH(c), MPH

Biography

Manley's undergraduate degree is in Chemistry – Pre-Medical Sciences. He completed Masters' of Science degrees in both Neuroscience and Clinical Research, a Masters in Public Health – Epidemiology concentraton, and a Ph.D. in Neuroscience while working full-time in the pharmaceutical industry. Manley is currently completing a Dr.P.H. in Epidemiology at Capella University. Manley has over 8 years academic research in the epidemiology of chronic diseases including CNS disorders, Cardio-metabolic diseases, and HIV/AIDS. Manley is an active member of the APHA Epidemiology Section; he is the Chair of the Epidemiology Policy Committee, Co-Chair of the Mental Health Committee, and reviews abstracts, papers, and sessions for various epidemiology journals. He is the current Secretary of the International Joint Policy Committee of the Societies of Epidemiology. Manley currently volunteers as the Executive Director of the HIV Nutrition Network, a not for profit HIV Advocacy Group promoting healthy nutrition amongst those with HIV/AIDS.

Manley has an in-depth knowledge of the pharmaceutical, biotech, medical device, and nutraceutical industry and has been involved in all stages of product development planning in Phases I through IV; including product portfolio management, targeted product profile design; protocol authorship and development, clinical research administration, HEOR, and medical safety monitoring. He has over 18 years in the industry in Clinical and Medical Affairs, as well as 8 years academic and private collaborative research experience. Manley has authored over 38 clinical protocols and was the primary or sole author of 28; authoring key protocols for pharmaceutical, medical device and nutraceutical/healthcare products. Manley has robust expertise in the epidemiology of chronic disease, CNS and mental health disorders, Cardio-Metabolic disorders and related diseases, and hematology/oncology. He is often an invited chairperson and speaker at professional society meetings and seminars on these topics. Manley is well versed in publishing and presenting pharmaceutical, medical device and nutraceutical/healthcare product scientific research data; consequently he presents often in his areas of expertise.

Manley is an established expert in clinical program design and development, protocol design and authorship, clinical project management and trial optimization, GCP/ICH and CFR regulations, medical safety monitoring, study staff training and education, comprehensive patient recruitment strategies, and study center selection/activation and training. Manley has recruited, organized, and managed research centers and clinicians for Phase I through Phase IV studies for CROs and Sponsors, as well as DSHEA and FTC/FCC compliant claims research for healthcare product manufacturers. In addition, he possesses a wealth of expertise in planning and administrating all aspects of pharmaceutical, medical device, and nutraceutical/healthcare product clinical research trials, from product concept development to database lock across multiple therapeutic areas including life cycle management projects.

Manley's other strengths are a strong background in Medical Affairs, Marketing and BD, Marketing Research Data Analysis, Brand Development, Health Economics Outcomes Research, and Community Based Health Outcome Initiatives. His areas of expertise within Medical are medical communications, KOL identification, relationship building, and optimization; MSL program management and training, expert panels and ad boards, and Medical Affairs administration. He has established KOL contacts and collaborative research efforts in the fields of CNS, mental health, and psychiatry; diabetes, metabolism/CVD; hematology, hemato-oncology.

His personal research interests include the areas of HIV/AIDS, Neurology/Psychiatry, hematology and cardio-metabolic diseases. Manley's areas of private epidemiological research expertise and publications are i) the role of clinical nutrition in disease state mediation, ii) cognitive impairment and mood affect disorders mediated by metabolic dysfunction, trauma, and surgery, iii) chronic diseases, CVD, and diabetes, and iv) emerging chronic diseases. Manley also publishes in the area of clinical trial optimization, clinical research participant recruitment and research center optimization and administration.