The 4th Clinical Project Management Training
(Basic to Intermediate Level)

September 18-20, 2014
New City Garden Hotel | Suzhou, China

DIA China will conduct the fourth CPM training on Sep. 18-20, 2014 in Suzhou.

This 3-day training course is designed to meet the increasing demands for knowledge and skills for all aspects of a clinical trial process. In this course the instructor Dr. Manley R. Finch, and other experts will share their working experience and approaches in designing, planning, budgeting, and executing clinical trials. Participants will also engage in extensive round-table discussions with case studies.

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

TARGETED AUDIENCE

- 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

FEATURED TOPICS

- 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

PROGRAM CHAIRPERSON

Qing'an JIAO, MD, MSc
Senior Director, Head of GCO China Global Clinical Operations
Xi'an Janssen Pharmaceuticals Ltd.

MAIN INSTRUCTOR

Manley R. FINCH, PhD, MPH, MSc
President and CEO C3 - Comprehensive Clinical Consultants & Executive Director HIV Nutrition Network, NPO & Chair Public Health Policy Committee,
Co-Chair Mental Health Committee APHA Epidemiology Section, Secretary, International Joint Policy Committee - Societies of Epidemiology

PROGRAM COMMITTEE

Paul DAI, MD
Senior Director, Regional Head of ICRO AMAC & Greater China Region, Beijing Novartis Pharma Co., Ltd.

Ning XU, MD, MBA
Executive Vice President, Head of Clinical Development and Regulatory Affairs, ZaiLaboratory

Sunny ZHU, MD
Global Clinical Development, Anti-infectives, GD Asia, BHC

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Manley R. FINCH, PhD, MPH, MSc
President and CEO C3 - Comprehensive Clinical Consultants & Executive Director HIV Nutrition Network, NPO & Chair Public Health Policy Committee,
Co-Chair Mental Health Committee APHA Epidemiology Section,
Secretary, International Joint Policy Committee - Societies of Epidemiology

Manley has 19 years of expertise in leading and directing Clinical and Medical Affairs departments in the pharmaceutical, biotech, medical device, and nutraceutical industry. Manley is an expert in clinical development program design, clinical program management, and protocol design authoring 38 protocols and being lead author on 28. 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.

PROGRAM CHAIRPERSON

Qing'an JIAO, MD, MSc
Senior Director, Head of GCO China
Global Clinical Operations
Xi'an Janssen Pharmaceuticals Ltd.

Dr. QingAn JIAO is currently Senior Director, Head of GCO China, Global Clinical Operations (GCO), at China R&D Center of Xi'an Janssen Pharmaceuticals Ltd., a pharmaceutical company of Johnson & Johnson. He has over 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 and clinical operations team in China and in Asia Pacific. Prior to joining Janssen, he was taking different management or senior management roles in China or Asia Pacific R&D Center at Roche, Sanofi, MDS Pharma Services and Pfizer, managing medium or large sized clinical operations team, with extensive experience in the management of multinational clinical trials in China and in Asia Pacific. He received his Medical degree in 1986 and Master degree in Medical 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 Advisory Council of China (ACC).

PROGRAM COMMITTEE

Paul DAI, MD
Senior Director, Regional Head of ICRO AMAC & Greater China Region, Beijing Novartis Pharma Co., Ltd.

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 16 years in couple of big pharma companies like Novartis, Eli Lilly and GSK. He graduated from medical school of Peking University and then became cardiologist in Beijing Cardiovascular and Lung Disease Research Center and Beijing Anzhen Hospital. He got deeply involved in clinical development and medical affairs in variety of the therapeutic areas including CVS, neuroscience, Hepatitis B, diabetes, respiratory, oncology and anti-infectious diseases in China. Dr. DAI participated in many scientific conferences as speaker/panelist.

Ning XU, MD, MBA
Executive Vice President, Head of Clinical Development and Regulatory Affairs, ZaiLaboratory

Dr. Ning Xu is currently the Executive Vice President, Head of Clinical Development and Regulatory Affairs, ZaiLaboratory. Dr. Xu has many years of experience of clinical research both in pharmaceutical and CRO industries. He had worked for pharmaceutical companies such as J&J and GSK as well as CROs such as Covance, Excel Pharma Studies and Parexel US. Dr. Xu is the Chairman of DIA China Advisory Council of China (ACC) and a DIA global board of director.

Dr. Xu got his M.D. from Peking Union Medical Colleague 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 got his MBA from the University of Illinois at Chicago in 2000.

Sunny ZHU, MD
Global Clinical Development, Anti-infectives, GD Asia, BHC

Sunny ZHU is appointed now as Global Clinical Lead Global Clinical Development of Bayer Healthcare Company for leading clinical development on a pipeline drug. Before this role, Sunny had worked in AstraZeneca for 10 years and left there as Executive Director, Development Project and Portfolio Management and was responsible for the development strategy and its execution for the new product pipeline and portfolio. Sunny is graduated from Peking University Medical School as a medical doctor and worked in Center of Disease Control of Beijing and then gained a master degree later on bio-statistics from the same university. Sunny has over 16 years rich experiences in big pharmaceutical industry with two major big companies, MSD and AstraZeneca for doing drug development work. She had worked on over 40 new drug development projects from various therapeutic areas including but not limited to respiratory and inflammation, oncology, cardiovascular, psychiatry & neuroscience, GI etc and had been appointed various positions such as Clinical Research Manager for China, Clinical Development Director for AsiaPac and Global Project Manager for Global Product Team. She has over 10 years experiences in clinical research and 5 years in new product development strategy and project management which to lead cross R&D functional team for a drug project. Sunny also had one and half year assignment in UK working for Astrazeneca global R&D center as the project manager role in global product teams to manage two oncology drug development projects.

DAY 1 | THURSDAY, SEPTEMBER 18

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

- Welcome
- Introductions
- Course objectives

9:00 – 9:45 **MODULE 1: Why Clinical Project Management?**

- Successes in biopharmaceutical product development
- Challenges facing biopharmaceutical product development
- Opportunities in biopharmaceutical product development

9:45 – 11:00 **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 **Refreshment Break**

11:00 – 12:00 **MODULE 3: Defining the Clinical Project Scope**

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

12:00 – 13:00 **Lunch**

13:00 – 15:00 **MODULE 4: Planning the Work**

- Breaking down the work: Sub-projects, work packages & deliverables
- GROUP EXERCISE: All big things can be broken down into small things
- Work package list & descriptors
- Work package durations
- GROUP EXERCISE: Credit card estimate

15:00 – 15:15 **Refreshment Break**

15:15 – 16:15 **MODULE 4: Planning the Work (continued)**

- Creating a network map
- SMALL GROUP EXERCISES: Post-it Note Exercise

16:15 – 16:30 **DAY 1 REVIEW, CHECK-IN, & 'HOMEWORK'**

DAY 2 | FRIDAY, SEPTEMBER 19

8:30 – 9:00 **DAY 1 REVIEW**

- Homework discussion

9:00 – 10:45 **MODULE 5: Estimating Enrollment**

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

10:45 – 11:00 **Refreshment Break**

11:00 – 12:00 **MODULE 6: Producing the Schedule**

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

12:00 – 13:00 **Lunch**

13:00 – 14:30 **MODULE 7: Determining the Project Staffing Plan**

- GROUP EXERCISE: Draw a picture of a team
- High performance teams
- High performance team charter
- Resource allocation
- Resource analysis
- SMALL GROUP EXERCISES

14:30 – 14:45 **Refreshment Break**

14:45 – 16:15 **MODULE 8: Clinical Project Risk Management**

- Risk assessment
- Risk control
- SMALL GROUP EXERCISE

16:15 – 16:30 **DAY 2 REVIEW, CHECK-IN, & 'HOMEWORK'**

DAY 3 | SATURDAY, SEPTEMBER 20

8:30 – 9:00 **DAY 1 & 2 REVIEW**

- Homework review

9:00 – 10:30 **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 **Refreshment Break**

10:45 – 12:00 **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 & tricks

12:00 – 13:00 **Lunch**

13:00 – 15:00 **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 ....

15:00 – 15:15 **Refreshment Break**

15:15 – 16:00 **MODULE 12: Clinical Trial Close-out**

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

16:00 – 16:30 **Wrap-up**

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

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Exchange Knowledge

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What Are DIA Communities?

DIA Communities are discipline-specific global societies of industry, academic, and regulatory professionals who collaborate with one another and share best practices.

Benefits

- Join a global community where members can share common experiences and knowledge and connect with others in their particular field.
- Gain exclusive access to DIA ConneX, our new interactive, global,
  professional networking tool. Every DIA Community has its own DIA Connex home page through which members can:
  - Share breaking news with community members
  - Store, organize and manage community information and documents
  - Participate in online discussions grouped by issues and topics, ask and answer questions, and share expertise to develop best practices
  - Manage their own community experience based on their professional profiles
  - And more

How Do I Join?

Joining a DIA community is easy, convenient, and free as part of your DIA membership.

Go to **www.diahome.org/Community** to join the DIA community of your choice.