Clinical Trials Project Management

Asia Pacific 2009

a Hands-On Clinical Masterclass

- **Master Clinical Research Concepts**
- **Hone Project Management Planning & Tracking Skills**
- **Conduct Efficient and Successful Clinical Trials**
- **Optimize Processes and Resources**
- **Implement Best Practices in Project Planning**

5 – 6 October 2009,
Concorde Hotel Singapore
Singapopre

Successful clinical trial management involves mastery of a range of skills and knowledge of a multitude of issues and tasks required to overcome hurdles in managing finance, people, work and time. This Clinical Trials Project Management course is run by an industry expert who shares with you many years of essential knowledge and personal experience gained from tackling the demands of developing and running clinical trials.

Course Highlights:

- Determine and define your role in project management and drug development
- Learn from the best practices in project planning
- Deliver results within project timelines
- Review the acute demands in tracking and metric data
- Inspect the most significant requirements in running ethical clinical trials
- Examine options in managing project deliverables and presenting results to managers
- Measure site performance
- Apply performance metrics to improving performance
- Analyse how to best use and manage your resources
- Gain insight into managing investigator and CRO budgets

Course Director:

Peter A S Motteram

International Clinical Trials Project Management Consultant

Organised by:

Connecting industry professionals worldwide
Registration No: 200707851H

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Why you should attend

Your ability to manage all aspects of a clinical trial has significant impact on the cost and time taken to develop a drug or device. Clinical project managers must have the necessary skills set, tools kit, knowledge and understanding of best practices in order to manage the trial outcome from the start. You must also have the additional ability to act, respond and adapt to arising situations during a trial's progress. This course will help you to successfully manage your clinical research projects within GCP guidelines and FDA regulations. Common pitfalls and challenges associated with clinical trials will be identified and discussed. You will take away tips, techniques and loads of insider information on managing clinical trials that can be adapted instantly to your projects. This course is designed to be interactive and encourages exchange of ideas between peers. It primarily enables you to obtain optimal benefit from the course director's wealth of experience and knowledge. Problem-solving guidance on essential activities such as effective and comprehensive study planning and substandard data will be addressed. How to adapt and apply concepts and principles to achieve desired goals will be illustrated through presentation, discussion and interactive works.

Clinical Trials Project Management is a hands-on interactive course that aims to provide detailed knowledge on skills, tools and best practices that will enable you to meet your project goals efficiently and effectively.

Why you should attend

By the end of the course, attendees should be able to:

- Define project management and understand the differences between the role of project management and a senior clinical role
- Explain the key elements of a clinical trial
- Apply measurement and control to project timelines and tasks
- Describe different management methods and how they operate to achieve project control
- Practise the measurement and control of staff re-sourcing and expenses
- Cite aspects of project management from budget management to operational delivery
- Set investigator and CRO budgets and stay within budgets
- Apply the project management methods best suited for your type of organization
- Apply these principles to managing a sub-contractor
- Know how to document your system

Registration commences at 8.00 am on Day One. Course begins from 9.00 am to 5.00 pm for all days. There will be mid-morning and mid-afternoon refreshments. Lunch will be served from 12.30 pm to 2.00 pm each day.

Day One, 5 October 2009

Before the course commences, think about the following issues:

- What is the role of and impact of Project Management in Drug Development?
- What are the common mistakes and pitfalls of Project Management in Drug Development?
- How can the project manager ensure timely and smooth completion?
- What are the challenges of Project Management in a regulated environment?
- How can the project manager be confident of the quality of all deliverables, when some of the disciplines within the project team may involve skills and expertise the project manager has never been trained in?
- If you have burning issues you wish to know, bring up at the outset of the course.

Introduction

- Welcome and Introduction.

Module 1

- Definition of clinical trials project management.
- Roles and responsibilities of Project Managers and differing areas of influence for a project managers in disparate organisations
- Forming a project plan.
- Development of Detailed Study Specification Worksheets
- Course definition of project management.
- Timelines and flow charting
- Worked example
- Constructing the project timeline
- Understanding dependencies and critical path
- Clarification of Project Scope

Module 2

- Controls and how to control a project.
- Choosing which items and processes to control.
- Measurement of a project.
- Developing objective criteria for project attributes.

Module 3

- Reporting on a project.

- Worked example
- Obstacles to implementation

Module 4
- Organisational structures.
- Assigning responsibility for project operations.
- Define individual roles appointed to each team member during each stage of a clinical trial
- How to operate in a team environment with members from diverse organizational set-ups
- Implementation of corrective action

Module 5
- Working exercise: project management for a clinical trial process.

Day Two, 6 October 2009

Module 6
- Review of Day One and questions arising.
- Analyse tracking and metric data
- Progress vs. control reporting.

Module 7
- Contract vs. project management
- Capacity planning and resource allocation.
- Appropriate resourcing of your trial
- Conflict resolution.
- Budgets and timesheets.
- Developing investigator site and sponsor (inc. CRO) budgets
- Worked example

Module 8
- Project management and CTMS tools.
- Timeline analysis and management
- Managing budget variances and Out of Scopes
- Managing a project team
- Define team roles
- Communications: Effective communication skills for project management
- Project team meeting management

Module 9
- Provider Management (e.g. CRO, site).
- Documenting your project management system.

Conclusion
- Review of Days 1 and 2. Wrap-up/Evaluations

About the Expert Trainer:

Peter Motteram, International Clinical Trials Project Management Consultant, has more than 20 years pharmaceutical, contract research organisation and consultancy experience including two of the then top five international CROs, interim management placement at a privately owned CRO, and many business and operations consulting projects. He brings a wealth of expertise and knowledge that includes consulting with clinicians, researchers and regulators on designing, planning, settting up and running successful clinical trials. Indeed, he has also authored a book, “Conducting Clincial Trials in Emerging Markets”, having worked in emerging economies including India, Eastern Europe and Russia. After working in a London teaching hospital, he started his pharmaceutical work at Sterling Research Group as GCP Quality Assurance auditor. Presently, Head of the Association of Clinical Research Professionals (UK) where he frequently & personally trains clinical research staff, Peter has also held senior appointments with Quintiles and ClinTrials Research in Quality Assurance, Business Development and as General Manager.

Who Should Attend:

This course is for clinical research professionals, both those who directly manage clinical trials and those working through other organisations such as CROs. Whether you have a clinical role as a Clinical Research Associate, Clinical Study Manager, Project Manager or Director-level position, this 2-day programme will provide you with the intensive training needed to improve your project management skills.. Attendees new to project management will receive an introduction to project management of clinical trials, whereas those more familiar with project management will receive a boost to their knowledge and further their understanding of how sponsor and CRO companies operate. Others who could benefit: ● medical director ● pharmaceutical development personnel ● contract management personnel ● project manager ● project team leader ● project coordinator

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Registration Form

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CLINICAL TRIALS PROJECT MANAGEMENT ASIA PACIFIC 2009 (CR0110)

	7% GST	Total
☐ EARLY BIRD FEE USD 1400 / SGD 2030 *(register & pay before 4 September 2009)*	SGD 142.10	SGD 2172.10
☐ NORMAL RATE USD 1600 / SGD 2320 *(register & pay after 4 September 2009)*	SGD 162.40	SGD 2482.40

Fee quoted are nett and exclusive of all taxes. A 7% GST is applicable for all Singapore registered companies.

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Contact name for payment confirmation (if different from above)

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VENUE INFORMATION

Concorde Hotel Singapore
100 Orchard Road
Singapore 238840
Tel: 65 6733 8855 / 65 6739 8339
Fax: 65 6235 0743
Contact person: Ms Katherine Koh
Email: katherine.koh@concorde.net

PAYMENT DETAILS:

☐ CHEQUE I enclose a cheque made payable to **Magenta Global Pte Ltd** for _____

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Payment by telegraphic transfer must be made payable to **Magenta Global Pte Ltd** Account No: 651-883761-001, Swift Code: OCBCSGSG, OCBC Bank, Robinson Road Branch, 77 Robinson Road, Robinson 77 #01-03, Singapore 068896

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HOW TO BOOK:

Tel : Leo 65-63912544

FAX : **65-6392 2102 / 63923592**

EMAIL your details to us at **leo@magenta-global.com.sg**

POST the completed form together with payment to **Magenta Global Pte Ltd**, 20 Kallang Avenue, Level 2 Pico Creative Centre, Singapore 339411.

BOOKING CONDITIONS

Full payment must be received prior to the event for entrance to be guaranteed. If payment is not received a personal credit card will be required to allow entry.

A confirmation letter and invoice will be sent to you on receipt of your booking. If you are unable to attend, a substitute delegate is always welcome. If you cancel your place in writing 10 working days before the event, a cancellation fee of 10% shall be applicable. Thereafter cancellations are not refundable.

It may be necessary for reasons beyond the control of the organizers to alter the content, timings or venue. The company will not accept liability for any transport disruption or any claims whatsoever and in such circumstances the normal cancellation restrictions apply.

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