This course covers integrated project management for clinical trial managers

**Course Overview**

This course includes many practical examples and case studies which allow the course participants to independently work to perform effective clinical project management after participation in this course.

Pharmaceutical industry’s need for faster and more cost efficient clinical drug development does not only require Clinical Study Managers’ solid knowledge and experience in planning and performance of the increasingly complex clinical trials but the management of these trials could substantially benefit from application of project management strategies, techniques and tools. This course teaches the tools and techniques of project management as outlined in various project management standards and how to utilise them successfully in clinical trial management.

In two independent modules of 3 days each, all internal and external clinical trial management areas will be covered:

- Project Definition and Organisational Context
- Project Management Tools and Techniques
- Scope Management, Resource Estimating and Budget Management of a Clinical Study
- Project Quality Management
- Project Risk Management
- Communication and Stakeholder Management
- Procurement Management
- Leadership Skills

The course is based on Alexander Gissler’s concept for Clinical Project Management.

**Who Will Attend**

This course is designed for experienced clinical project leaders who wish to get a deeper understanding of project management and on how the respective tools and techniques can be successfully implemented in their daily work.

The course level is intermediate to advanced. Attendees with 2 years of experience or more in managing clinical studies will take most advantage from these contents.
Clinical Project Management
Part I and Part II

Part I - Key Topics

- Project Definition and Organisational Context
- Project Management Strategies, Techniques and Tools
- Defining the Scope of a Project
- Resourcing and Scheduling
- Budgeting & Controlling

Part I - Learning Objectives

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

- Define a project, and differences in organisational structures as well as their impact on leading a clinical study
- Processes required to successfully plan, execute, monitor and control, as well as close-out a complex clinical study
- Define, plan, manage and verify the scope of a clinical study
- Define, plan, manage and verify the scope of a clinical study, estimate the resource needs and sequencing activities to produce a project schedule (Network Diagram and Gantt Chart)
- Estimate budgets for clinical studies and control budgets by the Earned Value Technique

Part II - Key Topics

- Quality Management
- Procurement
- Project Team Management
- Communication and Stakeholder Management
- Risk Management
- Lessons Learned
- Leadership Skills

Part II - Learning Objectives

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

- Efficiently plan and manage the quality of a complex clinical trial
- Manage study team and stakeholders in the clinical trial process
- Acquire, develop, manage, and motivate the study team, including subcontractors and remote international team members
- Plan and execute formal and informal communication, including reporting. Identify and manage stakeholders, including reporting to stakeholders
- Identify risks, estimate their probability, determine their impact, plan contingencies and quantify the budgetary requirements for these contingencies
- Plan and manage recording of lessons learned to improve best clinical study management practice within your organisation and/or globally
- Identify different soft skills required to be a great clinical study manager, e.g. negotiation skills, leadership without authority, motivational skills, etc.
Part I:
September 23-25, 2009, Prague, Czech Republic
ID# 09558

The DIA has blocked a limited number of rooms at the:

Hotel Century Old Town Prague
Na Porici 7 - 110 00 Prague 1, Czech Republic
Tel.: + 420 266 000 388
Fax: + 420 266 000 247

at the special rate of EUR 125.00 including breakfast, service and VAT.

To reserve a room, please call the hotel mentioning the reservation No. 98 139 or use the booking form on the DIA website.

IMPORTANT: To be assured of accommodation at the Hotel Century Old Town Prague, registrants are recommended to complete their reservation by August 8, 2009 at the latest.

Register for upcoming DIA training courses in 2009
The DIA offers courses in the following curricula areas:

**Clinical Research**

- Essentials of Clinical Study Management
  September 16-18, 2009 / Copenhagen, Denmark / ID# 09546
  December 2-4, 2009 / Basel, Switzerland / ID# 09550

- Clinical Project Management - Part I
  September 23-25, 2009 / Prague, Czech Republic / ID# 09558

- Clinical Project Management - Part II
  February 10-12, 2010 / Paris, France / ID# 10523

- Practical GCP Compliance Auditing of Trials & Systems
  October 7-9, 2009 / London, UK / ID# 09548

- Clinical Statistics for Nonstatisticians
  October 8-9, 2009 / London, UK / ID# 09549

**Non-Clinical Sciences**

- Non-Clinical Safety Sciences and their Regulatory Aspects
  November 23-27, 2009 / Lisbon, Portugal / ID# 09551

**Safety and Pharmacovigilance**

- Excellence in Pharmacovigilance:
  Clinical Trials and Post Marketing
  October 12-16, 2009 / Berlin, Germany / ID# 09527

- Medical Approach in Diagnosis and Management of ADRs
  September 17-18, 2009 / Paris, France / ID# 09532

- Practical Guide for Pharmacovigilance:
  Clinical Trials and Post Marketing
  November 18-20, 2009 / Paris, France / ID# 09547

**European Regulatory Affairs**

- European Regulatory Affairs
  September 10-11, 2009 / Frankfurt, Germany / ID# 09539
  November 19-20, 2009 / Paris, France / ID# 09540

- Building the eCTD
  September 17-18, 2009 / Copenhagen, Denmark / ID# 09542

- An Introduction to Product Information Management (PIM)
  October 15-16, 2009 / Berlin, Germany / ID# 09535

**US Regulatory Affairs**

- CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
  November 1-3, 2009 / Dubai, United Arab Emirates / ID# 09556

- US Regulatory Affairs
  October 19-22, 2009 / Basel, Switzerland / ID# 09525

For information on specific courses visit www.diahome.org:
- Click on Educational Offerings > Type the ID number into the keyword search field > Click on Find.
- For a list of all our training courses visit www.diahome.org:
  - Click on Educational Offerings > Select Region ‘Europe’ and Event Type ‘Training Course’ > Click on Find.
**REGISTRATION FORM**
Clinical Project Management
Part I and Part II

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

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**NOTE:** Payment of registration fees must be received before commencement of the training course.
Cancellations must be made in writing and be received at the DIA Europe office by 17:00 CET on September 16, 2009.

### HOW TO REGISTER

**Please indicate your professional category:**
- [x] Government/Academia
- [ ] Industry
- [ ] Contract Service Organisation

**Payment Methods**
- [ ] Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.
- [ ] VISA
- [ ] MC
- [ ] AMEX

- [ ] Cheques should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

- [ ] Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to “Account Holder: DIA.” including your name, company, Meeting ID# as well as the invoice number to ensure correct allocation of your payment. Payments must be net of all charges and bank charges must be borne by the payer.

Persons under 18 are not allowed to attend DIA meetings.

### CANCELLATION POLICY

Cancellations received by the date above are subject to an administrative fee:

- [ ] Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 Government/Academia/Non-profit (Member/Non-member) = € 100.00. Registrants who do not cancel by the date above and do not attend will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. DIA reserves the right to alter the venue and dates if necessary.

### Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable.

Please notify the DIA office of any such substitutions as soon as possible.

**IMPORTANT:** Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA.
If you have not received your confirmation within five working days, please contact the DIA in Europe.

**Payment of registration fees must be received before commencement of the training course.**
Cancellations must be made in writing and be received at the DIA Europe office by 17:00 CET on February 3, 2010.

**TOTAL AMOUNT DUE:** €

**Register for Part I and II of this training course and receive a 25% discount on the registration fee**

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**HOW TO REGISTER**

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