Clinical Project Management Part I

This course covers integrated project management for clinical trial managers

Faculty

Jennifer Kealy, BSc MPH
Managing Director, Cascade Clinical Consulting, France

Ingrid Klingmann, PhD MD
Managing Director, Pharmaplex bvba, Belgium

Who Will Attend

This training course is geared toward professionals who desire a comprehensive foundation in clinical project management. Participants should have at least two years of clinical trial experience, or have completed the DIA training course "Essentials of Clinical Study Management".

This "Clinical Project Management" training course is targeted at an intermediate/advanced level.

Course #10544 - Part I
September 22-24, 2010
Ramada Plaza, Basel, Switzerland

Course Overview

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.

This course provides a comprehensive foundation in clinical project management. Using the Project
Management Body of Knowledge (PMBOK®) as a guide, participants will be taught how to apply project management strategies, tools and techniques to their clinical trial projects.

In two independent modules of three days each, the following topics will be covered:

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

This course includes many practical examples and case studies which will enable participants to successfully implement and manage their own clinical trial projects effectively.

The course is based on Alexander Gissler's (PMP, Project Management Consultancy and Training) concept for Clinical Project Management.

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Key Topics

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

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 trial
- Identify the processes required to successfully plan, execute, monitor and control as well as close-out a complex clinical trial
- Define, plan, manage and verify the scope of a clinical trial, estimate the resource needs and sequencing activities to produce a project schedule (Network Diagram and Gantt Chart)
- Estimate and control budgets for clinical trials

DAY 1

08:00 **Registration**

08:45 **Welcome and Introduction of Participants**

09:15 **Session 1**

WHY PROJECT MANAGEMENT?
Ingrid Klingmann, Pharmaplex bvba, Belgium

10:30 **Coffee Break**

11:00 **Session 2**

PROJECT MANAGEMENT FRAMEWORK
Jennifer Kealy, Cascade Clinical Consulting, France

12:30 **Lunch Break**

13:30 **Session 3**

CASE STUDY: PROTOCOL PRESENTATION
Ingrid Klingmann, Pharmaplex bvba, Belgium

14:00 **Session 4**

INTEGRATION MANAGEMENT CONCEPTS
Ingrid Klingmann, Pharmaplex bvba, Belgium

15:00 **Coffee Break**

15:30 **Session 4 (continued)**

INTEGRATION MANAGEMENT CONCEPTS
Jennifer Kealy, Cascade Clinical Consulting, France

17:30 **Drinks Reception**

18:30 **End of Day 1**

DAY 2

08:30 **Session 5**

SCOPE MANAGEMENT
Jennifer Kealy, Cascade Clinical Consulting, France

10:00 **Coffee Break**

10:30 **Session 5 (continued)**

SCOPE MANAGEMENT
Ingrid Klingmann, Pharmaplex bvba, Belgium

12:00 **Lunch Break**

13:00 **Session 6**

SCHEDULING
Jennifer Kealy, Cascade Clinical Consulting, France

15:00 **Coffee Break**

15:30 **Session 6 (continued)**

SCHEDULING
Ingrid Klingmann, Pharmaplex bvba, Belgium

17:30 **End of Day 2**

DAY 3

09:00 **Session 7**

BUDGETING AND CONTROLLING
Ingrid Klingmann, Pharmaplex bvba, Belgium

10:30 **Coffee Break**

11:00 **Session 7 (continued)**

BUDGETING AND CONTROLLING
Jennifer Kealy, Cascade Clinical Consulting, France

12:30 **Lunch Break**

13:30 **Session 8**

PM DISASTER AVOIDANCE
Ingrid Klingmann, Pharmaplex bvba, Belgium
Jennifer Kealy, Cascade Clinical Consulting, France

16:00 **End of Training Course**

HOTEL INFORMATION

Course #10544 • Part I
September 22-24, 2010 • Basel, Switzerland

The DIA has blocked a limited number of rooms at the:
Ramada Plaza Basel Hotel
Messeplatz 12
4058 Basel, Switzerland
http://www.ramada.com/Ramada/control/Booking/property_info?propertyId=15756

Tel.: +41 61 560 40 00 Fax: +41 61 560 55 55

at the special rate of CHF 249.00 single occupancy CHF 279.00 double occupancy
including breakfast, service and VAT but excluding CHF 3.20 city tax.

To reserve a room, please call the Reservations Department on +41 61 560 40 00 referring to the DIA Training Course on "Clinical Project Management" or use the booking form on the DIA website.

IMPORTANT: To be assured of accommodation at Ramada Plaza Basel Hotel, registrants are recommended to complete their reservation by August 24, 2010 latest.

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD) at the European Medicines Agency
Courses throughout the year | European Medicines Agency, London, UK and selected European cities
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on Related Courses

Non-Clinical Research

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

Clinical Project Management - Part I
September 22-24, 2010 - Basel, Switzerland

www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY	MEMBER			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 7.6%	TOTAL	FEE	VAT 7.6%	Membership	TOTAL	FEE	VAT 7.6%	TOTAL
Industry	€ 1'785.00	€ 135.66	**€ 1'920.66** ❑	€ 1'785.00	€ 135.66	€ 115.00	**€ 2'035.66** ❑	€ 1'900.00	€ 144.40	**€ 2'044.40** ❑
Government/Academia (Full-Time)	€ 893.00	€ 67.87	**€ 960.87** ❑	€ 893.00	€ 67.87	€ 115.00	**€ 1'075.87** ❑	€ 1'008.00	€ 76.61	**€ 1'084.61** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course

Please indicate your areas of professional interest:

10544DIA

- ❑ AH - Academic Health Centres
- ❑ AM - Alternative / Herbal Medicine
- ❑ BT - Biotechnology
- ❑ CD - Clinical Data Management
- ❑ CH - Chemistry / Drug Design
- ❑ CL - Clinical Laboratory Data
- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
- ❑ DE - Devices
- ❑ DM - Document Management
- ❑ FI - Finance
- ❑ EC - e-Clinical
- ❑ GC - GCP
- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
- ❑ IM - Information Management
- ❑ IMP - Impact
- ❑ IS - Investigator Site
- ❑ IT - Information Technology / e-Business
- ❑ LA - Legal Affairs
- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
- ❑ MH - Managed Healthcare
- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
- ❑ NC - Non-clinical Safety & Efficacy / Toxicology
- ❑ NH - Natural Health Products
- ❑ OS - Outsourcing / Virtual Development
- ❑ OT - Over the Counter
- ❑ PC - Pharmaceutics
- ❑ PD - Professional Development
- ❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
- ❑ PP - Public Policy / Law
- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
- ❑ ST - Statistics / Biostatistics / Mathematical Modelling
- ❑ TR - Training
- ❑ VA - Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

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Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **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**

Card Number

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ **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# 10544 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 must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations 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 five working days prior to the course start date and do not attend, will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants are responsible for cancelling their own hotel and travel reservations.

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 Europe 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 DIA.**

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA European Office Postfach, 4002 Basel, Switzerland