DIA Training Course on

Clinical Project Management Part I

Course #12572 3-5 December 2012 Hotel MGallery am Konzerthaus, Vienna, Austria



Course Faculty

Alexander Gissler, PMP Managing Director ProjectPharm Limited, Germany

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

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

Instructors onsite will be selected from the full Faculty

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.

This course covers integrated project management for clinical trial managers

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

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 on Clinical Project Management.

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

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MONDAY | 3 DECEMBER 2012

08:00 REGISTRATION

08:45 Welcome and Introduction of Participants

09:00 Session 1

PROJECT MANAGEMENT FRAMEWORK

During this session participants will learn the definition of a project, understand the difference between project work and production, and identify how project management should fit into their business. We will briefly also touch upon programme and portfolio management. In addition, we will discuss how – depending on the nature of the organisation – the project management context can change, together with the role and responsibility of the project manager.

10:30 COFFEE BREAK

11:00 Session 1 (continued)

PROJECT MANAGEMENT FRAMEWORK

12:00 Session 2

CASE STUDY: PROTOCOL PRESENTATION

12:30 LUNCH

13:30 Session 3

INTEGRATION MANAGEMENT CONCEPTS

Project Integration Management, one of the Project Management Body of Knowledge (PMBoK's) (knowledge areas) is about identifying, defining, combining, unifying, and coordinating the 42 (formerly 44) project management processes as defined by PMBoK. Particular emphasis is given to developing two fundamental project documents: the project charter, and the project management plan.

15:00 COFFEE BREAK

15:30 Session 3 (continued)

INTEGRATION MANAGEMENT CONCEPTS

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

TUESDAY | 4 DECEMBER 2012

08:30 Session 4

SCOPE MANAGEMENT

During this session, participants will learn how to develop a project scope management plan, and how to implement it, thereby planning the project scope as well as verifying and controlling the scope. Particular emphasis will be given to the development of the Work Breakdown Structure (WBS) and the WBS dictionary, with examples of their practical implementation in the daily work of the project manager. The project scope, as defined by the WBS, is the basis for all further project planning for all other PMBoK areas, and is also continuously affected by the respective planning, execution and/or monitoring and controlling activities.

10:00 COFFEE BREAK

10:30 Session 4 (continued)

SCOPE MANAGEMENT

12:00 LUNCH

13:00 Session 5

PROJECT TIME MANAGEMENT

This session covers all processes and knowledge required to understand how to create a project schedule, either manually or with the help of software. Scheduling also covers resource estimating, algorithms for estimating durations, tools and techniques to control the schedule, as well as ways to accelerate the project timelines with the respective implications for the project (e.g. increased costs or risks)

15:00 COFFEE BREAK

15:30 Session 5 (continued)

PROJECT TIME MANAGEMENT

17:00 END OF DAY TWO

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

WEDNESDAY | 5 DECEMBER 2012

09:00 Session 6

PROJECT COST MANAGEMENT

Participants will learn how to estimate costs for individual activities or work packages, and how to develop a project budget (forecast). Thereafter we will focus on understanding the basic algorithms of Earned Value Analysis; the most widely accepted technique for project cost controlling.

10:30 COFFEE BREAK

11:00 Session 6 (continued)

PROJECT COST MANAGEMENT

12:30 LUNCH

13:30 Session 7

PM DISASTER AVOIDANCE

16:00 END OF TRAINING COURSE

DIA 2012 Training Courses in Clinical Research

Advanced GCP Study Monitoring

5 November 2012 | Paris, France | ID 12585

Clinical Project Management - Part I

3-5 December 2012 | Vienna, Austria | ID 12572

■ Clinical Project Management - Part II

20-22 February 2013 | Berlin, Germany | ID 13501

Clinical Statistics for Non-Statisticians

25-26 October 2012 | Nice, France | ID 12567

■ Essentials of Clinical Study Management

14-16 November 2012 | Paris, France | ID 12570 17-19 April 2013 | Vienna, Austria

■ Practical GCP Compliance Auditing of Trials and Systems

17-19 October 2012 | London, United Kingdom | ID 12568

Quality Risk Management (QRM)

15-16 April 2013 | Amsterdam, The Netherlands

HOTEL INFORMATION

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

Hotel MGallery am Konzerthaus

Am Heumarkt 35-37 1030 - VIENNA AUSTRIA

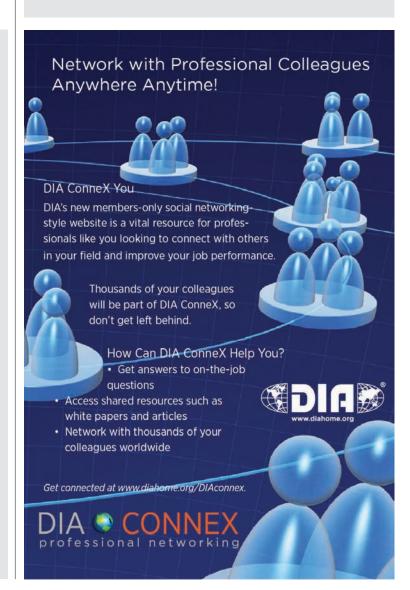
Email: H1276@accor.com Tel: (+43)1/716160 Fax: (+43)1/71616844 at the special rate of:

EUR 148.00 per room inclusive of breakfast, service and VAT. To make your reservation please:

Email: H1276@accor.com Tel: (+43)1/716160 Fax: (+43)1/71616844

To reserve a room, please use the booking form available on the DIA website.

Important : Please complete your reservation by 6 November 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.



REGISTRATION FORM

Clinical Project Management - Part I





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. *All Fees are subject to the local Austrian VAT of 20%

CATEGORT	Member Fee			Non-Member	ree
Industry € 1'78		Industry € 1'900.00			
Government / Charitable / Non-profit / Academia (Full-Time) € 89		Charitable/Non-profit/Academia/Governn	nent (Full-Time)	€ 1'008.00	
Join DIA now to qualify for the member rate			Fee	€ 115.00	
TOTAL AMOUNT DUE: € NOTE: PAYMENT DUE 3		30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT			
GROUP DISCOUNT/SME RATES AV	VAILABLE - PLEASE CONTACT DIA EUROP	FOR MORE INFORMATION			
RESPONSIBILITY/INTEREST AREA Plea	ase select one Primary Interest Area (P) and one	Secondary Interest Area (S) by placing a P	or S on the appropriate line.		
CMC Medical Writing		Pr	Professional Education & Training		
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eClinical Outsourcing		Quality Assurance/Quality Control			
Clinical Research & Development Comparative Effecti		ctiveness/Health Re			
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SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE		☐ 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			
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outset, addisse, the Box		Date	Cardholder's Signature		
Postal Code City		☐ Cheques should be made payable to DIA and mailed together with a copy of the registration form			
		for identification to: DIA Europe, Kueche	ngasse 16, Postfach, 4002 Basel	, Switzerland	
Country	Telephone				
		☐ Bank transfers: When DIA completes yo			
Fax (Required for confirmation)		_	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 #12572 as well		
		 as the invoice number to ensure correct 		Meeting ID #125/	/2 as well
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Please enter your company's European VAT number:		Payments must be net of all charges an	Payments must be net of all charges and bank charges must be borne by the payer.		
Please indicate your professional category: ☐ Academia ☐ Government			-	- · ·	
	☐ Industry ☐ Contract Service Organisation				
CANCELLATION POLICY	Cancellations must be made in writing as	d be received at the DIA Europe office five	working days prior to the co	urse start date	
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Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = \leq 200.00 - Government/Academia/Non-profit (Member/Non-member) = \leq 100.00

Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you 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 registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

IMPORTANT:

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

HOW TO REGISTER

The DIA Europe 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

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