

DIA Training Course on

Clinical Project Management Part I

Course #13572

18-20 September 2013

Bildungszentrum 21 Hotel, Basel, Switzerland



Faculty

Alexander Gissler, PMP

Managing Director
ProjectPharm Limited, Germany

Angelika Karwoth

Senior Clinical Research Consultant
Angelika Karwoth GmbH, Germany

Jennifer Kealy, BSc MPH

Managing Director
Cascade Clinical Consulting, France

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.

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.

**This course has limited capacity.
Register early.**

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:

Part I:

- Project Definition and Organisational Context
- Project Management Tools and Techniques
- Scope Management, Resource Estimating and Budget Management of a Clinical Trial

Part II:

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

Clinical Project Management I and II are taught as two independent modules. Participants will gain the most benefit from the course if they enrol in both modules.

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.

Participants are requested to bring their own laptops for this hands-on training course. Software required: MS Excel 2007 or later, Open Project (free software available from www.sourceforge.net/projects/projectlibre).

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

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

PharmaTrain recognised



WEDNESDAY | 18 SEPTEMBER 2013

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| 08:00 | REGISTRATION |
| 08:45 | WELCOME AND INTRODUCTION OF PARTICIPANTS |
| 09:00 | Session 1 PROJECT MANAGEMENT FRAMEWORK <p>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.</p> |
| 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 <p>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.</p> |
| 15:00 | COFFEE BREAK |
| 15:30 | Session 3 (continued) INTEGRATION MANAGEMENT CONCEPTS |
| 17:30 | DRINKS RECEPTION |
| 18:30 | END OF DAY ONE |

THURSDAY | 19 SEPTEMBER 2013

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| 08:30 | Session 4 SCOPE MANAGEMENT <p>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.</p> |
| 10:00 | COFFEE BREAK |

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| 10:30 | Session 4 (continued) SCOPE MANAGEMENT |
| 12:00 | LUNCH |
| 13:00 | Session 5 PROJECT TIME MANAGEMENT <p>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)</p> |
| 15:00 | COFFEE BREAK |
| 15:30 | Session 5 (continued) PROJECT TIME MANAGEMENT |
| 17:00 | END OF DAY TWO |

FRIDAY | 20 SEPTEMBER 2013

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| 09:00 | Session 6 PROJECT COST MANAGEMENT <p>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.</p> |
| 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 |

ABOUT DIA

DIA is a neutral, global, professional, member-driven association of nearly 18,000 professionals involved in the discovery, development, and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well being worldwide. Headquarters are in Horsham, Pa., USA, with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India and Beijing, China. www.diahome.org.

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

HOTEL INFORMATION

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

Hotel Bildungszentrum 21

Missionsstrasse 21
4003 Basel
Switzerland
Tel.: +41 61 260 21 21
Fax: +41 61 260 21 22
Website: www.bildungszentrum-21.ch

at the rate of:

CHF 135.00 per room inclusive of breakfast, service and VAT exclusive of CHF 3.20 city tax.

To make your reservation, please contact the hotel directly on:

Tel: +41 61 260 21 21

Please quote the booking reference: "Clinical PM I".

IMPORTANT: The room rate is available until 25 June 2013 or until the group block is sold-out, whichever comes first.

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 during DIA Europe sessions is strictly prohibited without prior written consent from DIA Europe.

DIA 2013 Training Courses in Clinical Research

- **Advanced GCP Study Monitoring**
5-6 June 2013 | Basel, Switzerland | ID 13549
- **Clinical Aspects of Quality Risk Management and Quality by Design**
19-20 September 2013 | Basel, Switzerland | ID 13560
- **Clinical Project Management – Part II**
Dates and location to be confirmed
- **Clinical Statistics for Non-Statisticians**
24-25 October 2013 | London, United Kingdom | ID 13551
- **Essentials of Clinical Study Management**
17-19 April 2013 | Vienna, Austria | ID 13527
20-22 November 2013 | Paris, France | ID 13554
- **Practical GCP Compliance Auditing of Trials and Systems**
23-25 October 2013 | London, United Kingdom | ID 13548

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REGISTRATION FORM

DIA Training Course on Clinical Project Management Part I
18-20 September 2013 | Bildungszentrum 21 Hotel, Basel, Switzerland



ID #13572

FEES

| | Member* | Non-Member* |
|---|------------------------------------|------------------------------------|
| Industry | € 1785.00 <input type="checkbox"/> | € 1900.00 <input type="checkbox"/> |
| Academia/Charitable/Government/Non-profit (Full-time) | € 893.00 <input type="checkbox"/> | € 1008.00 <input type="checkbox"/> |
| Join DIA now to qualify for the member rate | € 115.00 <input type="checkbox"/> | |

*All fees will be subject to the Swiss VAT at 8 %

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

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to availability – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

TOTAL AMOUNT DUE: _____

Payment is due 30 days after registration and must be paid in full by commencement of the course.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

Prof Dr Ms Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

Please charge my VISA MC AMEX

Card N°

Exp. Date /

Cardholder's Name

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." Please include your name, company, Course ID # 13572 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on <http://www.diahome.org/EUTerms>

Date

Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event 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 or postponed, 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.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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