DIA Training Course on

Clinical Project Management Part II

Course #13501
25-27 November 2013
Mercure Hotel Stoller Zürich, Zurich, Switzerland

Faculty

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Managing Director, Cascade Clinical Consulting,France

Instructors onsite will be selected from the full Faculty

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.

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.

Key Topics

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

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.

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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DAY 1

08:00 REGISTRATION

08:45 WELCOME AND INTRODUCTION OF PARTICIPANTS

09:00 Session 1

WHY PROJECT MANAGEMENT / REVIEW OF THE PROJECT MANAGEMENT BODY OF KNOWLEDGE (PMBOK) FRAMEWORK

10:00 Session 2

HUMAN RESOURCES MANAGEMENT

Research has shown that demotivation and frustration in project teams is in most cases due to unclear responsibilities, vague timelines, and to high expectations, often due to assigning tasks to individuals who are not adequately qualified. Project Human Resources Management deals with these issues. During this session, participants will learn how to plan for adequate, project-specific training, how to ensure all project team members understand clearly their tasks, what the expected timelines are, and whom they need to refer to for support, be it on the technical or personal side, and to whom to report status and progress.

10:30 COFFEE BREAK

11:00 Session 2 (continued)

HUMAN RESOURCES MANAGEMENT

Group Exercise HR Management: responsibility assignment matrix

12:30 LUNCH

13:30 Session 3

QUALITY MANAGEMENT

In this session we will cover the roles and functions of quality assurance and quality control, and identify the project team members responsible for carrying out the respective tasks. Various QM techniques will be presented. Participants will learn how planning for quality will add efficiency to clinical trials, and how this knowledge area integrates with the other knowledge areas, in particular scope, time, risk, and procurement management. We will also touch upon inspections by authorities, focussing on the most frequent findings, and work on exercises in best practice for project quality management

15:00 COFFEE BREAK

15:30 Session 3 (continued)

QUALITY MANAGEMENT

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

DAY 2

08:30 Session 4

PROCUREMENT

More than 20% of Research and Development is being outsourced to CROs, not accounting for several other vendors involved in the clinical trial business, and these numbers keep increasing. However, at the same time, issues and conflicts are increasing. During this session we will review how to decide whether to outsource a trial in whole or in part, how to identify the best vendor; different contract models, their advantages and disadvantages, and how to best manage vendors, using tools and techniques learned during the other sessions

10:00 COFFEE BREAK

10:30 Session 4 (continued)

GROUP EXERCISE: CONTRACT EVALUATIONS; VENDOR COMPARISON AND SELECTION

Team presentations and justification for selection of Core Lab, IVRS, IMP vendors, and monitoring/DM

12:30 LUNCH

13:30 Session 5

COMMUNICATIONS MANAGEMENT

Stakeholder support is another key success factor for clinical trials. During this session we will conduct a stakeholder analysis, and discuss what is needed to keep all these stakeholders aligned to support the project. We will develop various status and progress reports, to keep all stakeholders informed, and discuss how we could introduce efficiency in compiling these reports on a regular basis, in order to ensure that the month-end reporting period dows not become a regular interval during which the project remains without effective and proactive leadership.

15:00 COFFEE BREAK

15:30 Session 5 (continued)

GROUP EXERCISE: STAKEHOLDER ANALYSIS; GENERATION OF COMMUNICATION PLANS

Team presentations

17:30 END OF DAY TWO

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DAY 3

09:00 Session 6

RISK MANAGEMENT AND CONTINGENCY PLANNING

Addressing potential threats to a project is as important as leading the project itself, in order to avoid surprises which can make the project turn in the wrong direction. Participants will learn how to identify, prioritise, address, and continuously manage project risks, including the development of a contingency budget which is to be re-assessed on a regular basis and may constitute a key performance indicator for projects at high risk.

10:30 COFFEE BREAK

11:00 Session 6 (continued)

GROUP EXERCISE: PERFORM RISK ANALYSIS AND PUT TOGETHER THE RISK MANAGEMENT PLAN (IMPACT ASSESSMENT)

12:30 LUNCH

13:30 Session 7

CLINICAL STUDY INSPECTION FINDINGS AND HOW THIS RELATES TO PROJECT MANAEGMENT AND IN PARTICULAR TO RISK MANAGEMENT AND QUALITY MANAGEMENT

14:15 Session 8

RESCUING PROJECTS: FINAL CASE STUDY

Team presentations on how they would rescue a clinical trial that is in trouble

15:45 WRAP UP

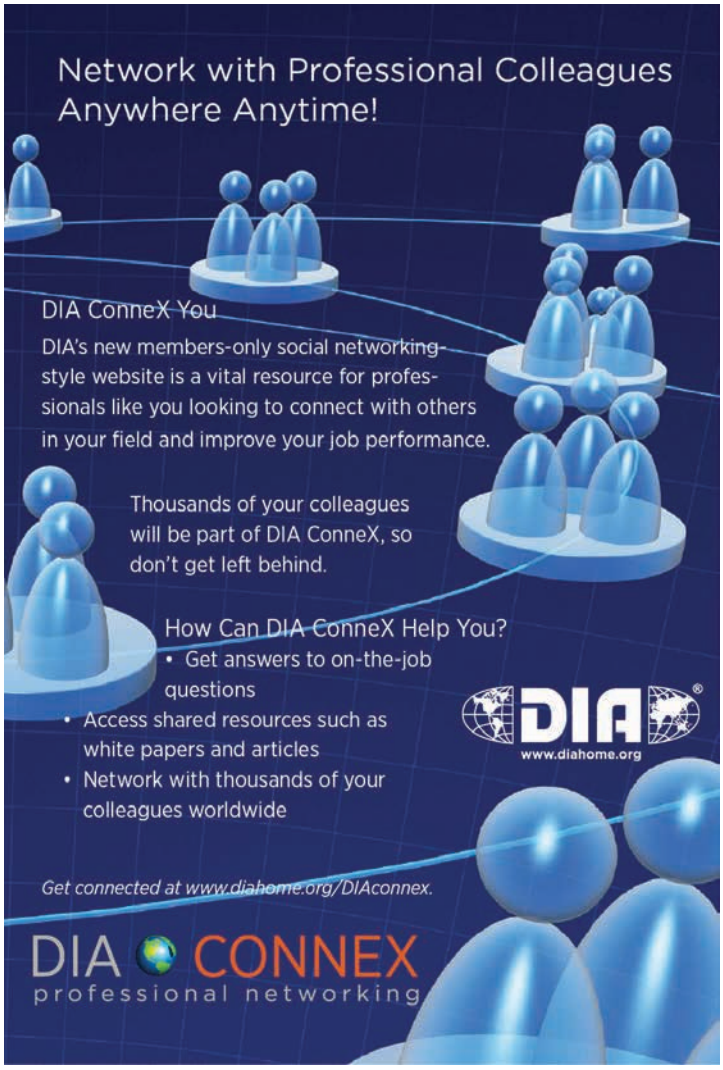
Summary of the processes within the PMBOK and pulling it all together

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.

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:

Mercure Hotel Stoller Zürich
Badenerstrasse 357
8040 Zürich
Tel: +41 (0)44 405 47 47
Fax: +41 (0)44 405 48 48
E-Mail: h5488@accor.com

at the rate of CHF 212.00 per room inclusive of breakfast and VAT.

In order to make your reservation please use the booking form available on the DIA website

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

REGISTRATION FORM

DIA Training Course on Clinical Project Management Part II
25-27 November 2013 Mercure Hotel Stoller Zürich, Zurich, Switzerland

www.diahome.org

ID #13501

FEES

	Member*	Non-Member*
Industry	€ 1'785.00 ❑	€ 1'900.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 893.00 ❑	€ 1'008.00 ❑
Join DIA now to qualify for the member rate	€ 115.00 ❑	

*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 avaibility – please contact DIA Europe for more information.

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

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

TOTAL AMOUNT DUE: _____

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 # 13501 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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