DIA Training Course on

Clinical Project Management Part I

Course #14542
22-24 September 2014
Hotel Novotel Paris Charenton, France

Faculty

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Instructors onsite will be selected from the full Faculty

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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.

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DAY 1

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

DAY 2

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

DAY 3

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

HOTEL INFORMATION

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

Hotel Novotel Paris Charenton
3-5 place des Marseillais
94227 Charenton Le Pont
France

Tel (+33)1/46766060
Fax (+33)1/49776800
E-mail H1549@accor.com
Website
http://www.novotel.com/gb/hotel-1549-novotel-paris-charenton/index.shtml

at the rates of EUR 150.00 per room inclusive of breakfast and exclusive of VAT. To make your reservation please use the hotel booking form available on the DIA website.

Important: The room rate is available until 29 August 2014 or until the group block is sold-out, whichever comes first.
In case of cancellation: The room can be cancelled 43 hours prior arrival, after that the credit card will be charged for the 1st night.
The Hotel Novotel Paris Charenton is located 10 minutes from Gare de Lyon train station, the vibrant Bastille district & Bercy. The liberté metro station (line 8) opposite the hotel gives direct access to Paris's main attractions like Place de la Concorde, Eiffel Tower, Opéra, etc.

About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation headquartered in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China.

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

New Clinical Trials Regulation and Transparency Requirements discussed at two-part Workshop in London

Clinical Trials Workshop I
Translating the **New Clinical Trials Regulation** into Practice
23-24 September 2014

Clinical Trials Workshop II
Translating the **New Transparency Requirements** into Practice
24-25 September 2014

Early-bird rates available. Register by **12 August to save!**

Visit www.diahome.org for more information or to register

REGISTRATION FORM

DIA Training Course on Clinical Project Management Part I

22-24 September 2014 | Hotel Novotel Paris Charenton, France

ID #14542

FEES

	Member*	Non-Member*
Industry	€ 1'840.00 ❑	€ 1'970.00 ❑
Academia/Charitable/Government/Non-profit (Full-time)	€ 920.00 ❑	€ 1'050.00 ❑
Join DIA now to qualify for the member rate	€ 130.00 ❑	

*All fees will be subject to the French VAT at 20 %

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.

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 # 14542 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.
Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Kuechengasse 16, 4051 Basel, Switzerland