

DIA Training Course on

Essentials of Clinical Study Management

Course #13554

27-29 November 2013

Paris, France Mercure Paris la Villette



Faculty

Patricia Fitzgerald

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Managing Director, Cascade Clinical Consulting, France

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Managing Director, SRS Schärer Research Services, Switzerland

Instructors onsite will be selected from the full Faculty

Featuring an esteemed European training faculty with over 100 years of combined experience in phase I-IV clinical trial management at big pharma, biotechnology firms, CROs and SMEs, as well as academic clinical research centres.

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.**

All you've ever wanted to know about Clinical Study Management... and more. Learn the Ins-and-Outs of Study Management, the Clinical Study Environment, and overall Drug Development.

Overview

The success of a clinical study is very much dependant on its efficient preparation and effective conduct. Study managers should be knowledgeable about required quality and regulatory standards, roles and responsibilities of team members, and be able to select and oversee internal and external resources. Study managers also should be able to anticipate potential problems, offer creative solutions and develop strategies to mitigate risk.

This training course provides a comprehensive overview of the essential elements of study management and the clinical study environment in the context of the overall drug development process. After successful completion of the training course, participants will be able to plan, execute and manage a clinical study from protocol to final report.

Key Topics

Featured topics include:

- Drug Development Process
- Feasibility Assessment
- Study Planning Tools
- Regulatory Framework
- Quality Management System
- Essentials of Site Management
- Resource Management
- Investigational Product Handling
- Risk Management
- Safety Reporting
- Study Evaluation and Reporting

Who Will Attend

This course will particularly benefit those newly appointed to, or interacting with, a clinical study management position, e.g. clinical research professionals with some basic experience in the field of clinical research, who need a broader understanding of the principles of clinical study management. This course will also benefit study managers in an academic research setting who interface with industry.

Level: Junior/Intermediate Level Clinical Research Professionals.

Learning Objectives

This course will provide proven strategies for preparing, launching and managing a clinical study from protocol to final report.

At the conclusion of this course participants should be able to:

- Describe the role of the study manager in reaching the study objectives
- Explain clinical research phases in drug development and describe basic concepts of study design
- Explain the regulatory framework in which studies are conducted and how compliance with the applicable regulations is achieved
- Identify the activities involved in study planning and start-up, including feasibility and budgeting.
- Qualify, select and oversee vendors and external resources for the study
- Identify various types of clinical trial communication plans.
- Describe the data management and statistical evaluation process and be able to manage the final study report preparation
- Recognise European safety reporting requirements
- Describe the quality management system
- Discuss risk management and contingency planning

PharmaTrain recognised



WEDNESDAY | 27 NOVEMBER 2013

08:00 REGISTRATION

08:30 INTRODUCTION

- The DIA
- The Faculty
- Learning Objectives
- Introduction to the Course

08:45 Session 1

DRUG DEVELOPMENT

- Inside a Pharmaceutical Company
- Drug Development Overview
- Clinical Development Phases
- Product Life Cycle

09:30 Session 2

QUALITY FRAMEWORK

- Introduction to ICH (GxP)
- Quality Management System
- Standard Operating Procedures
- Training

10:15 COFFEE BREAK

10:45 Session 3

REGULATORY OVERVIEW

- European Regulatory Environment
- Sponsor Responsibilities
- Clinical Trial Authorisation
- Ethical Review

11:45 Session 4

CLINICAL DEVELOPMENT

- The Clinical Development Plan
- Marketing Authorisation Application

12:30 LUNCH

13:30 Session 5

STUDY DESIGN

- Study Design Overview
- Basic Statistical Concepts

14:00 Session 6

STUDY PLANNING

- Project Planning
- Investigator Brochure
- Protocol Development

15:30 COFFEE BREAK

16:00 Session 6 (continued)

STUDY PLANNING

- Feasibility Assessment
- Enrollment Projections

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

THURSDAY | 28 NOVEMBER 2013

08:30 Session 7

RESOURCING

- Why and What to Outsource
- Scope of Work
- Request for Proposal
- Clinical Study Budgets
- Investigator Budgets
- Contracts
- Managing Teams
- Performance Measures

10:15 COFFEE BREAK

10:45 Session 7 (continued)

11:15 Session 8

STUDY PREPARATION

- Protocol and Amendment(s)
- Informed Consent
- Case Report Form
- Essential Documents
- Trial Master File
- Archiving

12:45 LUNCH

13:45 Session 9

IMP MANAGEMENT

- Definition of IMP
- Good Manufacturing Practice
- Manufacture
- Stability Testing
- Distribution
- Storage
- Accountability
- Destruction

14:45 Session 10

STUDY COMMUNICATION

- Communication Plans
- Effective Meetings and Teleconferences

15:45 COFFEE BREAK

16:15 Session 10 (continued)

STUDY COMMUNICATION

- Monitoring Reports
- Study Tracking
- Safety Reporting

17:00 END OF DAY TWO

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.

FRIDAY | 29 NOVEMBER 2013

08:30 Session 11

SITE MANAGEMENT

- Site Visits
- Identifying Warning Signs
- Audits and Inspections
- Misconduct

10:15 COFFEE BREAK

10:45 Session 12

EVALUATION AND REPORTING

- Data Management
- Statistical Analysis Plan
- Final Study Report
- Publication Rights
- Registries

11:45 Session 13

DRUG SAFETY

- Definitions and Regulations
- Responsibilities - Sponsor and Investigator
- Processing SUSARs
- Periodic Reporting
- Responsibilities - Independent Ethics Committees and Competent Authorities

12:30 LUNCH

HOTEL INFORMATION

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

Mercure Paris la Villette

216 Avenue Jean Jaurès
75019 Paris
France

Tel:+33 (0) 1 44 84 18 18

Fax:+33 (0) 1 44 84 18 20

Email: mercureparisv@alliance-hospitality.com

Website: <http://www.mercure.com/fr/hotel-8816-mercure-paris-la-villette/index.shtml>

at the rates of EUR 140.00 per room inclusive of breakfast and VAT.

To make your reservation, please use the hotel booking from available on the DIA website.

Important: The room rate is available until 9 October or until the group block is sold-out, whichever comes first.

Cancellation policy

No change or cancellation can be made after booking.

The client acknowledges that first night of the stay will be charged when the booking is made. This amount is non-refundable.

13:30 Session 14

RISK MANAGEMENT

- What is Risk Management?
- Risk Identification
- Assessment and Prioritisation of Risks
- Managing Risks
- Trends in Clinical Risk Management

14:30 CASE STUDY, DISCUSSION AND WRAP UP

15:30 END OF TRAINING COURSE

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DIA ConneX You
DIA's new members-only social networking-style website is a vital resource for professionals like you looking to connect with others in your field and improve your job performance.

Thousands of your colleagues will be part of DIA ConneX, so don't get left behind.

How Can DIA ConneX Help You?

- Get answers to on-the-job questions
- Access shared resources such as white papers and articles
- Network with thousands of your colleagues worldwide

Get connected at www.diahome.org/DIAconnex.

DIA CONNEX
professional networking

DIA
www.diahome.org

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.

REGISTRATION FORM

DIA Training Course on Essentials of Clinical Study Management
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ID #13554

FEES

	Member*	Non-Member*
Industry	€ 1'785.00 <input type="checkbox"/>	€ 1'900.00 <input type="checkbox"/>
Academia/Charitable/Government/Non-profit (Full-time)	€ 893.00 <input type="checkbox"/>	€ 1'008.00 <input type="checkbox"/>
Join DIA now to qualify for the member rate		€ 115.00 <input type="checkbox"/>

*All fees will be subject to the French VAT at 19.6 %

Please advise your European VAT number: _____

TOTAL AMOUNT DUE: _____

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.

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 # 13554 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.