

DIA Training Course on

Essentials of Clinical Study Management

Course #13527

17-19 April 2013

The Imperial Riding School Vienna, Vienna, Austria



Faculty

Mandy Bosch-Van De Pas

Managing Director, Per4mance Training & Coaching GmbH, Switzerland

Patricia Fitzgerald

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Senior Clinical Research Consultant, Angelika Karwoth GmbH, Germany

Jennifer Kealy

Managing Director, Cascade Clinical Consulting, France

Tamara Schärer

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 | 17 APRIL 2013

- 08:00 REGISTRATION**
- 08:30 INTRODUCTION**
- The DIA
 - The Faculty
 - Learning Objectives
 - Introduction to the Course
- 08:45 Session 1**
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- DRUG DEVELOPMENT**
- Inside a Pharmaceutical Company
 - Drug Development Overview
 - Clinical Development Phases
 - Product Life Cycle
- 09:30 Session 2**
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- QUALITY FRAMEWORK**
- Introduction to ICH (GxP)
 - Quality Management System
 - Standard Operating Procedures
 - Training
- 10:15 COFFEE BREAK**
- 10:45 Session 3**
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- REGULATORY OVERVIEW**
- European Regulatory Environment
 - Sponsor Responsibilities
 - Clinical Trial Authorisation
 - Ethical Review
- 11:45 Session 4**
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- CLINICAL DEVELOPMENT**
- The Clinical Development Plan
 - Marketing Authorisation Application
- 12:30 LUNCH**
- 13:30 Session 5**
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- STUDY DESIGN**
- Study Design Overview
 - Basic Statistical Concepts
- 14:00 Session 6**
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- STUDY PLANNING**
- Project Planning
 - Investigator Brochure
 - Protocol Development
- 15:30 COFFEE BREAK**
- 16:00 Session 6 (continued)**
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- STUDY PLANNING**
- Feasibility Assessment
 - Enrollment Projections
- 17:30 DRINKS RECEPTION**
- 18:30 END OF DAY ONE**

THURSDAY | 18 APRIL 2013

- 08:30 Session 7**
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- 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)**
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- 11:15 Session 8**
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- STUDY PREPARATION**
- Protocol and Amendment(s)
 - Informed Consent
 - Case Report Form
 - Essential Documents
 - Trial Master File
 - Archiving
- 12:45 LUNCH**
- 13:45 Session 9**
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- IMP MANAGEMENT**
- Definition of IMP
 - Good Manufacturing Practice
 - Manufacture
 - Stability Testing
 - Distribution
 - Storage
 - Accountability
 - Destruction
- 14:45 Session 10**
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- STUDY COMMUNICATION**
- Communication Plans
 - Effective Meetings and Teleconferences
- 15:45 COFFEE BREAK**
- 16:15 Session 10 (continued)**
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- 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 of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

FRIDAY | 19 APRIL 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

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

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.

Network with Professional Colleagues Anywhere Anytime!

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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

HOTEL INFORMATION

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

The Imperial Riding School, Renaissance Hotel

Ungargasse 60 Vienna, 1030 Austria

Tel.: (43)151518 52 Fax: (43) 1 515188720

Email: imperial.group.reservations@renaissancehotels.com

www.imperialrenaissance.at

at a special rate of:

EUR 140.00 per room per night.

The rates are including American Buffet Breakfast and excluding service charge and VAT.

METHOD OF RESERVATIONS

To guarantee the above noted guest room rates and availability. Reservations are to be made directly with Marriott by using the link available on DIA website.

IMPORTANT

To be assured of accommodation at the hotel, registrants are recommended to complete their reservation by 20 February 2013 the latest. Reservations received after this date will be subject to availability and room rate may vary.

REGISTRATION FORM

DIA Training Course on Essentials of Clinical Study Management
17-19 April 2013 | The Imperial Riding School Vienna, Vienna, Austria



ID #13527

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 Austrian VAT at 20 %

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

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

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 event.

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, Event # 13527 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.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

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:

- Full Meeting Cancellation: 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 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.