Essentials of Clinical Study Management

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.

Course #12570
14-16 November 2012
Mercure Paris Montmartre Sacre Cœur, Paris, France

Faculty

Ingrid Klingmann (Course Director)
Managing Director, Pharmaplex BVBA, Belgium

Mandy Bosch-Van De Pas
Managing Director, Per4mance Training & Coaching GmbH, Switzerland

Patricia Fitzgerald
Managing Director, Adamas Consulting, UK

Päivi Itkonen
Managing Director, Crown CRO Oy, Finland

Jennifer Kealy
Managing Director, Cascade Clinical Consulting, France

Deborah Malins
Managing Director, Russell QA Services Ltd., UK

Tamara Schärer
Managing Director, SRS Schärer Research Services, Switzerland

Instructors onsite will be selected from the full Faculty

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

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 18 credits.

This course has limited capacity. Register early.

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.

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.

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

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WEDNESDAY | 14 NOVEMBER 2012

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 | 15 NOVEMBER 2012

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

10:45 **COFFEE BREAK**

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 of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

FRIDAY | 16 NOVEMBER 2012

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**

HOTEL INFORMATION

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

Mercure Paris Montmartre Sacre Coeur
3 rue Caulaincourt
75018 - PARIS
France

Email: H0373@accor.com
Tel: 0033 8 258 0 7979 Fax: 0033 1 446 97071
Website: http://www.mercure.com/gb/hotel-0373-mercure-paris-montmartre-sacre-coeur/index.shtml

at the special rate of:
EUR 178.00 per standard room, single occupancy inclusive of breakfast buffet and VAT

To make your reservation please contact the hotel directly by using this link: (we will enter this info later on)

Important:
Please complete your reservation by 4 October 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

Cancellation:
Cancellations of reservations are possible until 73 hours prior to arrival. Any cancellation made less than 72 hours prior to arrival will be charged for the entire length of stay. No shows will be billed for the entire stay.

DIA Upcoming Training Courses in Clinical Research

Advanced GCP Study Monitoring
September 2012 | Location to be confirmed | ID 12585

Clinical Project Management – Part I
November 2012 | Location to be confirmed | ID 12572

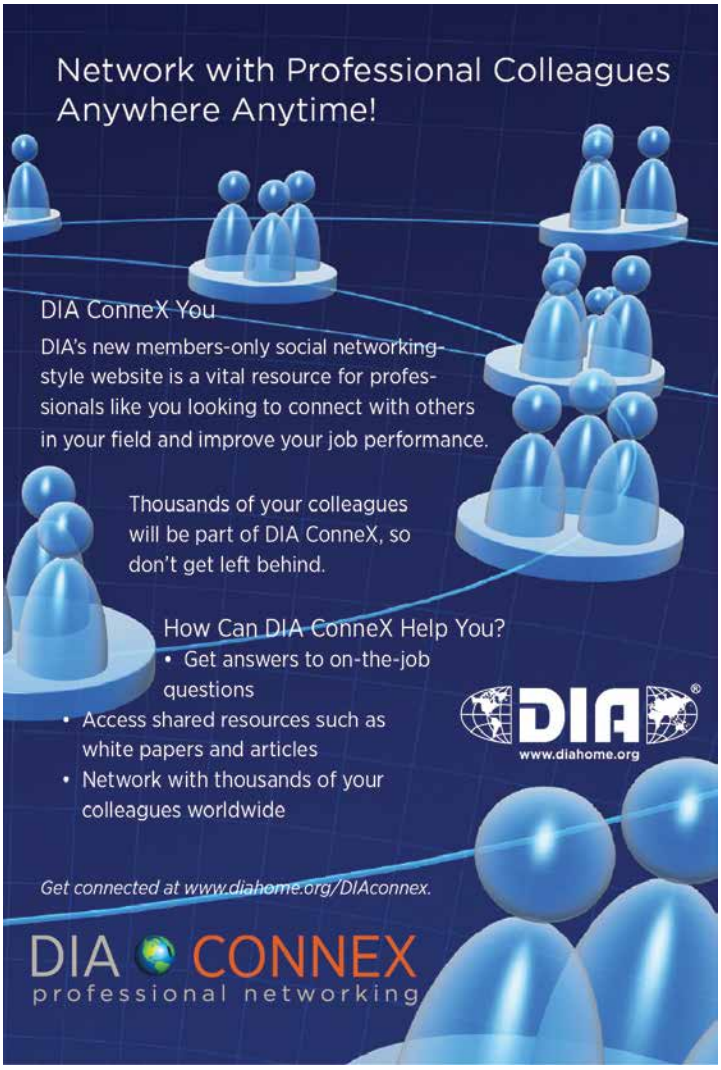
Clinical Project Management – Part II
22-24 February 2012 | Nice, France | ID 12554

Clinical Statistics for Non-Statisticians
October 2012 | Location to be confirmed | ID 12567

Essentials of Clinical Study Management
23-25 May 2012 | Munich, Germany | ID 12560
14-16 November 2012 | Paris, France | ID 12570

Practical GCP Compliance Auditing of Trials and Systems
17-19 October 2012 | London, United Kingdom | ID 12568

Health Technology Assessment (HTA)
May 2012 | Location to be confirmed | ID 12578



REGISTRATION FORM

Essentials of Clinical Study Management

14-16 November 2012 | Mercure Paris Montmartre Sacre Coeur, Paris, France

ID # 12570

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. Registration fees are inclusive of lunch and coffee breaks and other catering services to the amount of € 125.00. *All fees are subject to local French VAT of 19.6%

CATEGORY	Member Fee*		Non-Member Fee*
Industry	€ 1'785.00 ❑	Industry	€ 1'900.00 ❑
Academia/Government/Non-Profit (Full-Time)	€ 893.00 ❑	Academia/Government/Non-Profit (Full-Time)	€ 1'008.00 ❑

Join DIA now to qualify for the member rate — Fee € 115.00 ❑

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION 12570DIAWEB

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research & Development
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing
__ Non-clinical
__ Outsourcing
__ Comparative Effectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pricing/Reimbursement
__ Project Management
__ Professional Education & Training
__ Public Policy/Law
__ Quality Assurance/Quality Control
__ Regulatory Affairs
__ Statistics
__ IT/Validation

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required for confirmation)

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ VISA ❑MC ❑ AMEX

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Kuechengasse 16 Postfach, 4002 Basel, Switzerland

❑ **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 ID# 12570 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.

CANCELLATION POLICY

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 - Government/Academia/Non-profit (Member/Non-member) = € 100.00
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.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA Europe Postfach, 4002 Basel, Switzerland

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