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 #10528
10-12 November 2010
Lisbon, Portugal

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.

Course Faculty

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

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

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

Course 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 the participants will be able to plan, execute and manage a clinical study from protocol to final report.

Who Will Attend

Junior/Intermediate Level Clinical Research Professionals.
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.

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 | 10 NOVEMBER 2010

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 **RECEPTION**

18:30 **END OF DAY 1**

THURSDAY | 11 NOVEMBER 2010

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 2**

FRIDAY | 12 NOVEMBER 2010

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**

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

The New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2 Information Day at the European Medicines Agency
25 June 2010 | London, United Kingdom | ID 10568

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, UK and selected European cities
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

Essentials of Clinical Study Management

10-12 November 2010 - Lisbon, Portugal

ID# 10528

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

CATEGORY	MEMBER			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 20%	TOTAL	FEE	VAT 20%	Membership	TOTAL	FEE	VAT 20%	TOTAL
Industry	€ 1'785.00	€ 357.00	€ **2'142.00** ❑	€ 1'785.00	€ 357.00	€ 115.00	€ **2'257.00** ❑	€ 1'900.00	€ 380.00	€ **2'280.00** ❑
Government/Academia (Full-Time)	€ 893.00	€ 178.60	€ **1'071.60** ❑	€ 893.00	€ 178.60	€ 115.00	€ **1'186.60** ❑	€ 1'008.00	€ 201.60	€ **1'209.60** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course

Please indicate your areas of professional interest:

10528DIA

- ❑ AH - Academic Health Centres
- ❑ AM - Alternative / Herbal Medicine
- ❑ BT - Biotechnology
- ❑ CD - Clinical Data Management
- ❑ CH - Chemistry / Drug Design
- ❑ CL - Clinical Laboratory Data
- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
- ❑ DE - Devices
- ❑ DM - Document Management
- ❑ FI - Finance
- ❑ EC - e-Clinical
- ❑ GC - GCP
- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
- ❑ IM - Information Management
- ❑ IMP - Impact
- ❑ IS - Investigator Site
- ❑ IT - Information Technology / e-Business
- ❑ LA - Legal Affairs
- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
- ❑ MH - Managed Healthcare
- ❑ MN - Manufacturing: Drug Substance, Drug Product, Packaging
- ❑ MW - Medical / Scientific Writing
- ❑ NC - Non-clinical Safety & Efficacy / Toxicology
- ❑ NH - Natural Health Products
- ❑ OS - Outsourcing / Virtual Development
- ❑ OT - Over the Counter
- ❑ PC - Pharmaceutics
- ❑ PD - Professional Development
- ❑ PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
- ❑ PP - Public Policy / Law
- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
- ❑ ST - Statistics / Biostatistics / Mathematical Modelling
- ❑ TR - Training
- ❑ VA - Validation

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'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 to receive presentation download instructions)

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

PAYMENT METHODS

❑ **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

Exp. Date

Cardholder's Name

Date Cardholder's Signature

❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., Elisabethenanlage 25, 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." including your name, company, Meeting ID# 10528 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course 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

Registrants who do not cancel five working days prior to the course start date and do not attend, 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 registrants. Registrants 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 registrants 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. If you have not received your confirmation within five working days, please contact DIA.**

HOW TO REGISTER

The DIA 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 European Office Postfach, 4002 Basel, Switzerland