DIA Training Course on

Clinical Trial Management Essentials

Course #15557
2-4 November 2015
Dorint An der Messe, Basel, Switzerland

OVERVIEW

The success of a clinical trial depends on efficient preparation, effective conduct and oversight. This training course provides a comprehensive overview of the essential elements of clinical trial management and overall drug development process, using real case studies, practical examples and group exercises, After successful completion of the training course, participants will be able to plan, execute and manage a clinical study.

LEARNING OBJECTIVES

This course will provide the strategies and tools to prepare, launch and manage a clinical trial from protocol to final report.

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

- Describe the clinical research phases and basic concepts of study design
- Explain the regulatory framework in which studies are conducted
- 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

- Define performance metrics
- Identify various types of clinical trial communication plans
- Describe the data management and statistical evaluation process
- Manage the final study report preparation
- Recognise European safety reporting requirements
- Understand what a quality management system is and how to achieve compliance with ICH-GCP and applicable regulations
- Discuss risk management (including risk based monitoring) and contingency planning

WHO WILL ATTEND

This course will particularly benefit those newly appointed toa clinical study management position, e.g. monitors and 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 those who interact with clinical trial managers (such as IT, Finance, PV, QA and CTAs). as well as those in an academic research setting who interface with industry.

Level:

Clinical Research Professionals including CRAs, IT staff, Data Managers, Clinical Study Managers, Quality Management

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

DIA DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

COURSE FACULTY

Patricia Fitzgerald
Managing Director, Adamas Consulting, UK

Jennifer Kealy
Head of Quality Management Services,
Swiss Tropical & Public Health Institute,
Medicines Research Department, Switzerland

KEY TOPICS

- Study Evaluation and Reporting Drug Development Process
- Feasibility Assessments
- Study Planning Tools
- Regulatory Framework
- Quality Management System
- Vendor Selection
- Resource Management
- Investigational Product Handling
- Site Management
- Risk Identification and Mitigation
- Safety Reporting
- Study Evaluation and Reporting

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.

DAY 1

08:00 — **REGISTRATION**

08:30 — **INTRODUCTION**

- The DIA
- Learning Objectives
- Introductions

08:45 — **SESSION 1**

DRUG DEVELOPMENT
- 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 and Competency Assessments

10:15 — **COFFEE BREAK**

10:45 — **SESSION 3**

REGULATORY OVERVIEW
- European Regulatory Environment:the new EU Directive
- 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
- Adaptive designs, blinding, bias

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**

DAY 2

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 and Metrics

10:15 — **COFFEE BREAK**

10:45 — **SESSION 7 (CONTINUED)**

11:15 — **SESSION 8**

STUDY PREPARATION
- Informed Consent
- Case Report Forms
- Essential Documents
- Trial Master File
- Archiving

12:45 — **LUNCH**

13:45 — **SESSION 9**

IMP MANAGEMENT
- Definition of IMP
- Good Manufacturing Practice (GMP)
- Stability Testing
- Distribution
- Storage
- Accountability
- Destruction

14:45 — **SESSION 10**

STUDY COMMUNICATION
- Communication Plans
- Effective Meetings and Teleconferences
- Managing Cross Cultural Teams

15:45 — **COFFEE BREAK**

16:15 — **SESSION 10 (CONTINUED)**

STUDY COMMUNICATION
- Monitoring Reports
- Study Tracking
- Safety Reporting

17:00 — **END OF DAY TWO**

DAY 3

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

14:45 **END OF TRAINING COURSE**

COURSE VENUE

Dorint an der Messe
Schoenaustrasse 10
4058 Basel, CH
Tel: +41 61 6957 000
info.basel@dorint.comwww.hotel-basel.dorint.com

DIA has blocked a limited number of rooms at the rate of CHF 205.00 per single room per night including breakfast and W-lan internet. Upon arrival all guests will receive a Mobility Ticket, which allows them to use public transport in Basel during their stay free of charge. The City-Tax of CHF 3.50 per person and night will be charged additionally.

A cancellation free of charge is possible until +31 days prior to arrival.The room rate is available until the room block is sold-out, To make the hotel booking, please fill in the booking form available on the DIA website and send it per e-mail to info.basel@dorint.com.

REGISTRATION FORM

Clinical Trial Management Essentials # 15557

2-4 Novemeber 2015 | Basel, Switzerland

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REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and training course material. Please check:

FEES *	MEMBER	NON-MEMBER
INDUSTRY	€ 1'840.00 ❑	€ 2'000.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 920.00 ❑	€ 1'080.00 ❑
Join DIA now to qualify for the member rate	€ 130.00 ❑	

*All fees will be subject to the Swiss VAT at 8%

Please enter your Company's Swiss VAT number: _____

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

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit **www.DIAHome.org** and click on Membership for more details.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

The DIA Europe, Middle East & Africa Contact Center Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52
Email: diaeurope@diaeurope.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAhome.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East & Africa office four weeks 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 four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.
DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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 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 in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

email (Required for confirmation)

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 # 15557 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, Middle East & Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature