DIA Training Course on

Clinical Trial Management Essentials

19-21 September 2016
Paris La Défense Grande Arche, France

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 the 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 a deep insight into strategies and tools to prepare launch and manage a clinical trial from protocol to final report.

At the conclusion of this course, participants will have a clear understanding about:

- The clinical research phases and basic concepts of study design
- Clinical Trial start-up incl. Regulatory framework, Study planning, Budgeting
- Clinical Trial Conduct incl. Vendor management, Performance metrics, Communication plans, Risk management, Quality Management, Safety reporting requirements
- General data management, statistical evaluation process and requirements for final study report preparation

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

KEY TOPICS

Featured topics include:

- 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

WHO WILL ATTEND

This course will particularly benefit those newly appointed to a 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. The 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.

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

FACULTY

Päivi Itkonen
Managing Director, Crown CRO Oy, Finland

Angelika Karwoth
Senior Clinical Research Consultant, Angelika Karwoth GmbH, Germany

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INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 INTRODUCTION

- Learning Objectives
- Introductions

08:45 SESSION 1

DRUG DEVELOPMENT

- Drug Development Overview
- Clinical Development Phases
- Product Life Cycle

09:15 SESSION 2

QUALITY FRAMEWORK

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

10:00 COFFEE BREAK

10:30 SESSION 3

REGULATORY OVERVIEW

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

11:15 SESSION 4

CLINICAL DEVELOPMENT

- The Clinical Development Plan
- Marketing Authorisation Application

12:00 LUNCH

13:00 SESSION 5

STUDY DESIGN

- Study Design Overview
- Basic Statistical Concepts
- Adaptive designs, blinding, bias

13:30 SESSION 6

STUDY PLANNING

- Project Planning
- Investigator Brochure
- Protocol Development
- Working Protocol Introduction for ESM course

15:00 COFFEE BREAK

15:30 SESSION 6 CONTINUED

STUDY PLANNING

- Exercise on Working Protocol
- Feasibility Assessment
- Enrollment Projections

16:30 SESSION 7

STUDY PREPARATION

- Exercise on Working Protocol
- Informed Consent
- Case Report Forms
- Essential Documents
- Trial Master File
- Archiving

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

DAY 2

08:30 SESSION 8

RESOURCING

- Overview
  - Why and What to Outsource
  - Scope of Work
  - Request for Proposal
  - Clinical Study Budgets
  - Investigator Budgets
  - Calculate Budget
  - Contracts
  - Managing Teams
  - Performance Measures and Metrics
- Exercise on Working Protocol

10:15 COFFEE BREAK

10:45 SESSION 8 CONTINUED

11:45 SESSION 9

IMP MANAGEMENT

- Definition of IMP
- Manufacture vs Dispensing
- Distribution
- Storage
- Accountability
- Destruction

12:15 LUNCH

13:15 SESSION 10

STUDY COMMUNICATION

- Communication Plans
- Effective Meetings and Teleconferences
- Managing Cross Cultural Teams
- Exercise on Working Protocol
  - Monitoring Plan

15:00 COFFEE BREAK

15:30 SESSION 10 CONTINUED

STUDY COMMUNICATION

- Monitoring Reports
- Study Tracking

16:45 END DAY TWO

Day 3

08:30 SESSION 11

SITE MANAGEMENT

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

10:00 COFFEE BREAK

10:30 SESSION 12

RISK MANAGEMENT

- What is Risk Management?
- Exercise on ESM Protocol:
  - Risk Identification
  - Assessment and Prioritisation of Risks
  - Managing Risks
- Trends in Clinical Risk Management

12:30 LUNCH

13:30 SESSION 13

EVALUATION AND REPORTING

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

14:15 SESSION 14

DRUG SAFETY

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

14:45 END OF TRAINING COURSE

Follow **@DrugInfoAssn**

Training Course Venue

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

Paris La Défense Grande Arche
17/20 Esplanade Ch. de Gaulle -
Rue des Trois Fontanot
92000 Nanterre/Paris, France
Tel: +33 8 2580 5959
Fax: +33 1 4725 4624
Email: H1982@accor.com
Website

DIA has blocked a limited number of hotel rooms at the rate of EUR 180.00 per standard room per night including breakfast and VAT, excl. City-Tax.

If you would like to make a booking, please fill in the booking form and send it per email to H1982@accor.com with a reference "DIA".

The room rate is available until 19 August 2016 or until the room block is sold-out, whichever comes first.

How to get there: The hotel is located at the Nanterre-Prèfecture train station. From CDG airport take the blue train line B towards South, change at Chatelet Les Halles to red train line A towards West, and get off at Nanterre-Prefecture.

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

Continuing Education

DIA meetings and trainings 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 15.5 credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available.

SwAPP Swiss Association of Pharmaceutical Professionals

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

REGISTRATION FORM

Clinical Trial Management Essentials # 16557

19-21 September 2016 | Paris La Défense Grande Arche | Paris, France

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REGISTRATION FEES

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

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'870.00 ❑	€ 2'025.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 935.00 ❑	€ 1'090.00 ❑

All registration fees are subject to applicable French VAT

Please enter your company's French VAT number: _____

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

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

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

❑ I do not want complimentary membership

The DIA Europe, Middle East & Africa Contact Centre 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: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland
Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and 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

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.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

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) Attendee email (Required for course material access)

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 # 16557 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 and 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.diaglobal.org/EUTerms

Date	Signature