Advanced GCP Study Monitoring

Course #10561
19 November 2010
SAS Radisson Hotel, Boulogne-Billancourt (Paris), France

Course Faculty

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This course has limited capacity. Register early.

Course Overview

Clinical Research Monitors perform a critical role in the conduct of a clinical trial. As the primary liaison between the sponsor and the site, the monitor must verify that the clinical trial is conducted according to Good Clinical Practice, the safety and rights of subjects are protected, the Investigational Medicinal Product is handled correctly and the data is of the highest quality. This course will expand and strengthen the monitoring skills of Clinical Research Associates, enabling them to perform their role more proficiently and effectively.

Using case studies, monitors will learn how to handle monitoring problems and proactively manage risks before they become audit findings later. This course includes an invaluable "shared experience session" which will enable colleagues to discuss monitoring challenges they face.

Learning Objectives

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

- Describe the role and responsibilities of the monitor
- Evaluate source documents and electronic records competently
- Identify signs that suggest potential misconduct and fraud
- Manage monitoring risks proactively
- Apply Root Cause Analysis techniques when uncovering site problems
- Develop effective Corrective and Preventive Action Plans (CAPA)
- Assess the success of corrective action through benchmarking

Key Topics

- Research misconduct
- Risk Management for the Monitor
- Elements of Corrective and Preventive Action Plans
- Advanced Monitoring Techniques and Tools
- Benchmarking for site performance evaluation
- Source document/data evaluation
- Electronic source data verification

Who Will Attend

- Pharmaceutical, biotechnology and medical device industry
- Freelancers, self-employed
- Orientated towards the needs of CRAs with, say 2 – 3 years experience in the job who want to acquire advanced monitoring skills and/or refresh existing ones.
- Experienced CRAs
- Contract Research Organizations
- Study coordinators, interested in monitoring from the sponsor's perspective

Level of Course

Intermediate - Advanced

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08:30 **Welcome and Introductions**
Role and Responsibilities of the Monitor

09:00 **Session 1**
Research Misconduct and Fraud: Identifying the Risks

Sadly, research misconduct, or fraud, is more common than you might think. As an experienced monitor you will probably have met it, possibly without realising it. This session will help you learn how to detect research misconduct and, when you have, what you should do about it.

10:30 **Coffee Break**

10:45 **Session 2**
Monitoring Risk Management

Monitors are often confronted with a variety of problems during a clinical trial, including protocol non-compliance, issues with IMP handling and staff performance, to name a few. Many situations are avoidable, if identified and addressed early. Learn how to systematically assess risks and uncover real cause(s) of problems identified during monitoring visits, using Root Cause Analysis. By knowing the cause of the problem, you can then formulate an effective Corrective and Preventive Action Plan. Proactively manage risks in your study before it is too late.

12:15 **Lunch**

13:00 **Interactive Session:**
What are the Common Monitoring Problems? Solutions?

Bring your questions and challenges that you face in your role as a monitor. This is a unique opportunity to share experiences and learn from other monitors.

13:45 **Session 3**
Advanced Monitoring Techniques and Tools/ Benchmarking Improvement.

All too often, monitors get caught up in the details when performing Source Data Verification and fail to identify important trends and emerging risks that can lead to serious problems. Learn the common techniques GCP auditors use that can be applied during monitoring visits to identify trends early in a trial. The concept of benchmarking will be introduced as a way to assess site performance and improvement.

14:45 **Coffee Break**

15:00 **Session 4**
Source Document Evaluation

Good source documents are vital if you are to be able to prove the integrity of your site's study data to auditors and GCP inspectors. This session will refresh your memory on the basics of source data and provide you with tools to assist you in evaluating and monitoring both paper and electronic records.

16:30 **Wrap up**

Hotel Information

The DIA has blocked a limited number of rooms at the:
SAS Radisson Hotel Boulogne (Paris)
Av. Edouard Vaillant 33
92660 Boulogne-Billancourt - France

Tel.: + 33 1 46 08 87 28
Fax: + 33 1 46 08 87 29
Email: reservations.boulogne@radissonsas.com
http://www.radissonblu.com/hotel-parisboulogne

at a special rate of: Single Room EUR 190.00 Double Room EUR 190.00

This rate is per room, per night, VAT, service, taxes and buffet breakfast included. Please call the Reservations Department on + 33 1 46 08 87 22 to book a room mentioning the keyword "DIA – Advanced GCP Study Monitoring" or use the hotel booking form on the DIA website.

IMPORTANT: To be assured of accommodation at the SAS Radisson Hotel Boulogne, registrants are recommended to complete their reservation by October 20, 2010 latest. Reservations after that date are subject to availability.

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

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.

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REGISTRATION FORM

Advanced GCP Study Monitoring

19 November 2010 - SAS Radisson Hotel, Boulogne-Billancourt (Paris), France

ID# 10561

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. 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 19.6%	TOTAL	FEE	VAT 19.6%	MEMBERSHIP	TOTAL	FEE	VAT 19.6%	TOTAL
Industry	€ 770.00	€ 150.92	**€ 920.92** ❑	€ 770.00	€ 150.92	€ 115.00	**€ 1'035.92** ❑	€ 885.00	€ 173.46	**€ 1'058.46** ❑
Government/Academia (Full-Time)	€ 385.00	€ 75.46	**€ 460.46** ❑	€ 385.00	€ 75.46	€ 115.00	**€ 575.46** ❑	€ 500.00	€ 98.00	**€ 598.00** ❑

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

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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.

__ Advertising & Promotion
__ CMC
__ Clinical Data Management/ eClinical
__ Clinical Research
__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/Health Technology Assessment/Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
__ IT/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

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Street Address / P.O. Box

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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# 10561 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