

# Advanced GCP Study Monitoring

Course #10560

4 June 2010

Radisson SAS, Prague, Czech Republic



## Course Faculty

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## 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

This course has limited capacity.  
Register early.

<b>08:30</b>	<b>Welcome and Introductions</b> Role and Responsibilities of the Monitor	<b>13:00</b>	<b>Interactive Session:</b> <b>What are the Common Monitoring Problems? Solutions?</b>
<b>09:00</b>	<b>Session 1</b> <b>Research Misconduct and Fraud: Identifying the Risks</b>  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.		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.
<b>10:30</b>	<b>Coffee Break</b>	<b>13:45</b>	<b>Session 3</b> <b>Advanced Monitoring Techniques and Tools/ Benchmarking Improvement.</b>  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.
<b>10:45</b>	<b>Session 2</b> <b>Monitoring Risk Management</b>  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.	<b>14:45</b>	<b>Coffee Break</b>
<b>12:15</b>	<b>Lunch</b>	<b>15:00</b>	<b>Session 4</b> <b>Source Document Evaluation</b>  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.
		<b>16:30</b>	<b>Wrap up</b>

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA.

## Hotel Information

The DIA has blocked a limited number of rooms at the:  
Radisson SAS Alcron Hotel  
Štěpánská 40 - 110 00 Prague 1  
Czech Republic

Telephone: +420 2 22 820 000  
Telefax: +420 2 22 820 100  
www.radissonblu.com/hotel-prague

at the special rate of:

Single Room EUR 130.00      Double Room EUR 130.00

This rate is per room, per night, service, taxes and buffet breakfast included. 9% VAT is excluded.

To reserve a room, please use the hotel booking form on the DIA website or call the hotel.

**IMPORTANT:** To be assured of accommodation at the Radisson SAS Alcron Hotel, registrants are recommended to complete their reservation by May 1, 2010 latest. Reservations received 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](http://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 | Basel, Switzerland | ID 10563  
14-15 October 2010 | Paris, France | ID 10564

For more information and a complete listing of all training courses, please visit [www.diahome.org](http://www.diahome.org) and click on Training.

# REGISTRATION FORM

Advanced GCP Study Monitoring

4 June 2010 - Radisson SAS, Prague, Czech Republic

ID# 10560



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	€ 770.00	€ 154.00	€ 924.00	€ 770.00	€ 154.00	€ 115.00	€ 1'039.00	€ 885.00	€ 177.00	€ 1'062.00
Government/Academia (Full-Time)	€ 385.00	€ 77.00	€ 462.00	€ 385.00	€ 77.00	€ 115.00	€ 577.00	€ 500.00	€ 100.00	€ 600.00

**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.**

- |  |   |   |   |
|--|---|---|---|
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| <input type="checkbox"/> CMC                                 | <input type="checkbox"/> Medical Writing  | <input type="checkbox"/> Pricing/Reimbursement                          | <input type="checkbox"/> Research & Development |
| <input type="checkbox"/> Clinical Data Management/ eClinical | <input type="checkbox"/> Nonclinical  | <input type="checkbox"/> Project Management                             | <input type="checkbox"/> Statistics             |
| <input type="checkbox"/> Clinical Research                   | <input type="checkbox"/> Outsourcing  | <input type="checkbox"/> Professional Education, Training & Development | <input type="checkbox"/> Strategic Planning     |
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| <input type="checkbox"/> Manufacturing                       |   |   |   |

## REGISTRANT

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

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**Please indicate your professional category:** ☐ Academia ☐ Government

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## 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

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☐ **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., Elisabethen Anlage 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# 10560 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](http://www.diahome.org)

**Fax** +41 61 225 51 52

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