

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing

Course #10525

June 2-4, 2010

Radisson SAS Alcron Hotel, Prague, Czech Republic



Programme Chairs

Gaby Danan, MD, PhD

Expert, Senior Director Global Pharmacovigilance
and Epidemiology
sanofi-aventis, France

William Gregory, MD

Senior Director, Safety and Risk Management
Pfizer, USA

Jan Petracek

Scientific Administrator, European Medicines Agency,
EU

FDA Speaker Invited

Programme Committee

Harri Helajarvi, MD

Former Qualified Person for Pharmacovigilance
Finland

Bina Patel, BSc

Director, Case Management
Global Clinical Safety & Pharmacovigilance
GlaxoSmithKline, UK

This course has limited capacity.
Register early.

Course Overview

This is a basic overview course, intended for individuals who have limited experience in pharmacovigilance/drug safety monitoring. The focus will be on pharmacovigilance with traditional medicinal products, both investigational and marketed, intended for human use in clinical trials, in post marketing studies, and in the healthcare setting following product launch.

Who Will Attend - Beginner Level

Individuals with limited experience in the clinical safety/pharmacovigilance area. Those from the pharmaceutical industry, academia, regulatory authorities. Medical writers, marketing personnel, and those who need an overview of clinical safety and may interact with members of those departments.

Learning Objectives

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

- Identify the history, the principles and regulatory framework for clinical safety/pharmacovigilance
- Discuss the basic definitions of terms used in day-to-day work
- Recognise EU, US and international safety surveillance regulatory requirements
- Describe the criteria and elements of expedited and periodic reporting of drug safety from Phase I studies to post-marketing
- Demonstrate an awareness of risk management and pharmacoepidemiology

Key Topics

- Legal basis for safety reporting including a historical perspective
- Basic definitions and tools
- Data collection and processing in post marketing phase
- Medical evaluation
- Safety reporting requirements in pre-marketed phase
- A workshop and practical exercises
- Safety reporting requirements in the post marketing phase
- An introduction to risk communication
- Inspections in pharmacovigilance
- Introduction to risk management, epidemiological methods for signal detection and risk assessment

WEDNESDAY | JUNE 2, 2010

08:00 Registration

08:45 Introduction and Overview

09:00 SESSION 1

LEGAL BASIS FOR SAFETY REPORTING INCLUDING A HISTORICAL PERSPECTIVE

Session Chairs:

Gaby Danan, sanofi-aventis, France

Jan Petracek, European Medicines Agency, EU

Session 1 will provide a concise overview of the history, the principles and the regulatory framework for pharmacovigilance. The role of international consensus fora such as 'International Conference on Harmonisation' (ICH) and 'Council for International Organization of Medical Sciences' (CIOMS) working groups will also be described.

History of Pharmacovigilance and the Legal Basis for Safety Reporting

Jan Petracek, European Medicines Agency, EU

10:30 Coffee Break

11:00 SESSION 2

BASIC DEFINITIONS AND TOOLS

Session Chair:

Gaby Danan, sanofi-aventis, France

This session will feature an introduction to safety data collected from clinical trials phases I to IV, definitions, reporting tools, adverse event processing and reporting requirements, as well as an introduction to basics for signal detection and safety monitoring.

An Introduction to Safety Data, Reporting Processes, Detection and Monitoring

Bina Patel, GlaxoSmithKline, UK

12:30 Lunch

13:30 SESSION 3

DATA COLLECTION AND PROCESSING IN POST MARKETING PHASE

Session Chairs:

Gaby Danan, sanofi-aventis, France

Harri Helajarvi, Finland

Introduction to the collection and reporting of adverse events during the post marketing phase, i.e. basics of data to be collected and processed, reporting tools and formats used, adverse event follow-up and introduction to 'Medical Dictionary for Regulatory Activities' (MedDRA) used in safety reporting. Basics of post marketing aggregate reporting.

Safety Data Collection and Processing in Post marketing Phase, and Overview of MedDRA

Harri Helajarvi, Finland

15:00 Coffee Break

15:30 SESSION 4

MEDICAL EVALUATION

Session Chairs:

Gaby Danan, sanofi-aventis, France

Harri Helajarvi, Finland

The principles of the medical evaluation of single adverse event cases, things to consider, and methods used.

Medical Evaluation of Adverse Events

Harri Helajarvi, Finland

16:30

Exercise & Case Studies

Harri Helajarvi, Finland

Bina Patel, GlaxoSmithKline, UK

17:00

SESSION 5

AN INTRODUCTION TO RISK COMMUNICATION

Session Chair:

Jan Petracek, European Medicines Agency, EU

17:30

Reception

18:30

End of Day 1

THURSDAY | JUNE 3, 2010

09:00

SESSION 5 CONTINUED

AN INTRODUCTION TO RISK COMMUNICATION

Session Chair:

Jan Petracek, European Medicines Agency, EU

10:00

SESSION 6

SAFETY REPORTING REQUIREMENTS IN PRE-MARKETING PHASE

Session Chair:

FDA Speaker Invited

William Gregory, Pfizer, USA

10:30

Coffee Break

11:00

SESSION 6 CONTINUED

SAFETY REPORTING REQUIREMENTS IN PRE-MARKETING PHASE

Session Chair:

FDA Speaker Invited

William Gregory, Pfizer, USA

12:00

SESSION 7

WORKSHOP

A series of vignettes and exercises for pragmatic application of clinical safety concepts

William Gregory, Pfizer, USA

FDA Speaker Invited

12:30

Lunch

13:30

SESSION 7 CONTINUED

WORKSHOP

William Gregory, Pfizer, USA

FDA Speaker Invited

14:30

SESSION 8

SAFETY REPORTING REQUIREMENTS IN THE POST MARKETING PHASE

Session Chair:

FDA Speaker Invited

16:00

Coffee Break

16:30

Exercise & Case studies

FDA Speaker Invited

17:30

End of Day 2

FRIDAY | JUNE 4, 2010

09:00 **SESSION 9****INSPECTIONS IN PHARMACOVIGILANCE**

Session Chair:
FDA Speaker Invited

Panel Discussion on Audits and Preparations for Inspections:
Gaby Danan, sanofi-aventis, France
William Gregory, Pfizer, USA
FDA Speaker invited

10:30 **Coffee Break**11:00 **SESSION 10****INTRODUCTION TO EPIDEMIOLOGICAL METHODS, SIGNAL DETECTION AND RISK ASSESSMENT**

Session Chair:
Jan Petracek, European Medicines Agency, EU

12:00 **Lunch**13:00 **SESSION 11****RISK MANAGEMENT IN PHARMACOVIGILANCE**

Session Chair:
Jan Petracek, European Medicines Agency, EU

14:00 **Exercises & Case Studies**

Jan Petracek, European Medicines Agency, EU

14:45 **Wrap-up and Summary**15:00 **End of Training Course**

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

Tel.: +420 2 22 820 000
Fax: +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

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) at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, UK
For course details on EV, please visit www.diahome.org > Educational Offerings > 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

REGISTRATION FORM

ID# 10525

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
June 2-4, 2010 - Radisson SAS Alcron Hotel, Prague, Czech Republic



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 <input type="checkbox"/>	€ 1'785.00	€ 357.00	€ 115.00	€ 2'257.00 <input type="checkbox"/>	€ 1'900.00	€ 380.00	€ 2'280.00 <input type="checkbox"/>
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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:****10525DIA**

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<input type="checkbox"/> QC - Quality Control / Quality Assurance
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☐ **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# 10525 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