Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing

Course #10526
December 1-3, 2010
Marriott Rive Gauche, Paris, France

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-marketing 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

Credits
The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited the training course on ‘Practical Guide for Pharmacovigilance: Clinical Trials and Post-Marketing’ with 17.5 credits.
08:00 Registration

08:45 Introduction and Overview

09:00 SESSION 1
LEGAL BASIS FOR SAFETY REPORTING INCLUDING A HISTORICAL PERSPECTIVE

The Course starts with a concise overview of the history, the principles and the regulatory framework for pharmacovigilance. It includes introduction to the mechanisms of international consensus building through 'International Conference on Harmonisation' (ICH) and 'Council for International Organization of Medical Sciences' (CIOMS) working groups, as well as major trends in development of underlying technology and science.

Jan Petracek, PharmInvent, Czech Republic

10:30 Coffee Break

11:00 SESSION 2
BASIC PRINCIPLES, DEFINITIONS AND TOOLS

The second session features an introduction to safety data collected from clinical trials phases I to IV, definitions, reporting tools, adverse event processing and reporting requirements, and how to collate the data for signal detection and safety monitoring.

Jan Petracek, PharmInvent, Czech Republic

12:30 Lunch

13:30 SESSION 3
POST-MARKETING SAFETY DATA (WITH AN INTRODUCTION TO MEDDRA)

The third session (a) Explains the basics of data collection, processing, and reporting that pertain to Individual Case Safety Reports after a product is marketed; (b) Discusses the foundation for reporting aggregate safety data in the post-marketing phase; and (c) Describes the classification and analysis of medical concepts using MedDRA, the Medical Dictionary for Regulatory Activities.

William Gregory, Pfizer, USA

15:00 Coffee Break

15:30 SESSION 4
MEDICAL EVALUATION OF ADVERSE EVENTS

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

Gaby Danan, Pharmacovigilance Expert, France

16:30 Exercises & Case Studies

17:00 SESSION 5
AN INTRODUCTION TO RISK COMMUNICATION

Risk communication is a key tool for sharing the results of all the other laborious pharmacovigilance processes, a way of risk minimisation, a chance for improvement of benefit and risks of medicinal products. The session covers the major principles, communication channels and tools, communication planning, getting feedback, making adjustments, as well as organisational aspects of risk communication.

Jan Petracek, PharmInvent, Czech Republic

17:30 End of Day 1

THURSDAY | DECEMBER 2, 2010

09:00 SESSION 5 CONTINUED
AN INTRODUCTION TO RISK COMMUNICATION - EXERCISES

Participants will be asked to draft a communication plan and a Dear Healthcare Professional Letter in reaction to a major safety issue. The exercise will simulate the stress and emotions that are often involved in risk communication.

Jan Petracek, PharmInvent, Czech Republic

10:00 SESSION 6
PRE-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

The sixth session describes and illustrates the basic requirements for clinical safety data reporting from interventional clinical trials, including Individual Case Safety Reports and aggregate reports.

FDA Speaker Invited
William Gregory, Pfizer, USA

10:30 Coffee Break

11:00 SESSION 6 CONTINUED
PRE-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

FDA Speaker Invited
William Gregory, Pfizer, USA

12:00 Exercises and Case Studies

12:30 Lunch

13:30 Exercises and Case Studies Continued

14:30 Session 7
POST-MARKETING CLINICAL SAFETY DATA REPORTING REQUIREMENTS

The seventh session explains and illustrates the basic requirements for clinical safety data reporting in the post-marketing phase, including Individual Case Safety Reports and aggregate reports.

William Gregory, Pfizer, USA
FDA Speaker Invited

16:00 Coffee Break

16:30 Exercises & Case Studies

17:30 End of Day 2

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.
FRIDAY | DECEMBER 3, 2010

09:00 SESSION 8
INSPECTIONS IN PHARMACOVIGILANCE

Panel Discussion on Audits and Preparations for Inspections:
Gaby Danan, Pharmacovigilance Expert, France
Jan Petracek, PharmInvent, Czech Republic
William Gregory, Pfizer, USA
FDA Speaker invited

10:30 Coffee Break

11:00 SESSION 9
INTRODUCTION TO EPIDEMIOLOGICAL METHODS, SIGNAL DETECTION AND RISK ASSESSMENT

The session shows to participants how to apply basic epidemiological approaches needed in pharmacovigilance for interpretation of the study designs and results. The participants will also learn the current methods of signal detection and risk assessment, the essential parts of all scientific and medical pharmacovigilance jobs.

Jan Petracek, PharmInvent, Czech Republic

12:00 Lunch

13:00 SESSION 10
RISK MANAGEMENT IN PHARMACOVIGILANCE

Since 2005, the risk management of medicinal product is an active part of pharmacovigilance, providing tools for further risk characterisation and intervention to improve benefit/risk of a medicine. The instructor will explain the background of risk management in Europe, guide the participants through the EU-RMP structure and logic, and share practical experience, dos, and don’ts in risk management planning.

Jan Petracek, PharmInvent, Czech Republic

14:00 Exercises & Case Studies

Quick EU-RMP drafting exercise will engage participants in a real life scenario to experience challenges and discuss possible solutions that will help them in their current and future pharmacovigilance career.

14:45 Wrap-up and Summary

15:00 End of Training Course

Hotel Information

The DIA has blocked a limited number of rooms at the:

Marriott Rive Gauche
17, Blvd. Saint-Jacques
75014 Paris, France

Tel.: +33 (0) 1 40 78 79 80 - Fax: +33 (0) 1 40 78 78 05
www.marriott.com

at a special rate of EUR 179.00 per room per night for single occupancy. The rate includes buffet breakfast, service and VAT.

Please book your room online https://www.marriott.com/reservation/availability.mi?propertyCode=parst) and enter the Group Code: DCRD CRA to receive the special rate or call the hotel.

IMPORTANT: In order to profit of the special rate, registrants are recommended to complete their reservation at their earliest convenience at the Marriott Rive Gauche but no later than October 29, 2010.
# Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
**December 1-3, 2010 - Marriott Rive Gauche, Paris, France**

- 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.

## HOW TO REGISTER

**1.** Fax

- [0x0] Fax

**2.** Email

- [0x0] Mail

**3.** www.diahome.org

**4.** diaeurope@diaeurope.org

**5.** +41 61 225 51 52

**6.** DIA European Office

- Postfach, 4002 Basel, Switzerland

**7. **ID# 10526

### 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: € 200.00 - Government/Academia/Non-profit: € 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.

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Please indicate your areas of professional interest:

- AH - Academic Health Centres
- AM - Alternative / Herbal Medicine
- BT - Biotechnology
- CD - Clinical Data Management
- CH - Chemistry / Drug Design
- CL - Clinical Laboratory Data
- CM - CMC
- CP - Clinical Safety/Pharmacovigilance
- CR - Clinical Research & Development
- CS - Clinical Supplies
- DC - Dictionaries / Data Standards
- DE - Devices
- DM - Document Management
- FI - Finance
- EC - e-Clinical
- GC - GCP
- GE - Generic Manufacturing
- GL - GLP
- GM - GMP
- IM - Information Management
- IMP - Impact
- IS - Investigator Site
- IT - Information Technology / e-Business
- LA - Legal Affairs
- MA - Marketing / Advertising
- MC - Medical Communications / Information
- MH - Managed Healthcare
- MN - Manufacturing: Drug Substance, Drug Product, Packaging
- MW - Medical / Scientific Writing
- NC - Non-clinical Safety & Efficacy / Toxicology
- NH - Natural Health Products
- OS - Outsourcing / Virtual Development
- OT - Over the Counter
- PC - Pharmaceuticals
- PD - Professional Development
- PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- PH - Pharmacology
- PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- PM - Project Management
- PP - Public Policy / Law
- QC - Quality Control / Quality Assurance
- RA - Regulatory Affairs / Policy / Drug or Device Approval / GMP
- RD - Research & Development / Strategic Issues
- ST - Statistics / Biostatistics / Mathematical Modelling
- TR - Training
- VA - Validation

### 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

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<td>€ 893.00</td>
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**NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course.

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### REGISTRANT

Please complete in block capital letters or make registration even simpler by attaching the registrant’s business card here.

- **Prof.**  **Dr.**  **Ms.**  **Mr.**

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Please indicate your professional category:

- **[ ]** Industry
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