Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing

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

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

FDA Speaker Invited

EMEA 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

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WEDNESDAY | DECEMBER 1, 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
EMEA Speaker Invited

Session 1 will provide a concise overview of the history, the principles and the regulatory framework for pharmacovigilance. The role of international concensus 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
EMEA Speaker Invited

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:
EMEA Speaker Invited

17:30 **Reception**

18:30 **End of Day 1**

THURSDAY | DECEMBER 2, 2010

09:00 **SESSION 5 CONTINUED**

AN INTRODUCTION TO RISK COMMUNICATION

Session Chair:
EMEA Speaker Invited

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 | DECEMBER 3, 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:
EMEA Speaker Invited

12:00 **Lunch**

13:00 **SESSION 11**

RISK MANAGEMENT IN PHARMACOVIGILANCE
Session Chair:
EMEA Speaker Invited

14:00 **Exercises & Case Studies**
EMEA Speaker Invited

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:

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

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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: DCRDCRA 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.

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 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

ID# 10526

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.

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	€ 1'785.00	€ 349.86	**€ 2'134.86** ❑	€ 1'785.00	€ 349.86	€ 115.00	**€ 2'249.86** ❑	€ 1'900.00	€ 372.40	**€ 2'272.40** ❑
Government/Academia (Full-Time)	€ 893.00	€ 175.03	**€ 1'068.03** ❑	€ 893.00	€ 175.03	€ 115.00	**€ 1'183.03** ❑	€ 1'008.00	€ 197.57	**€ 1'205.57** ❑

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:

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- ❑ CM - CMC
- ❑ CP - Clinical Safety/Pharmacovigilance
- ❑ CR - Clinical Research & Development
- ❑ CS - Clinical Supplies
- ❑ DC - Dictionaries / Data Standards
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- ❑ GE - Generic Manufacturing
- ❑ GL - GLP
- ❑ GM - GMP
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- ❑ MA - Marketing / Advertising
- ❑ MC - Medical Communications / Information
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- ❑ 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 - Pharmaceutics
- ❑ PD - Professional Development
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- ❑ PH - Pharmacology
- ❑ PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- ❑ PM - Project Management
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- ❑ QC- Quality Control / Quality Assurance
- ❑ RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- ❑ RD - Research & Development / Strategic Issues
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- ❑ TR - Training
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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# 10526 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.

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