EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing training course

Course #13502
18-22 February 2013
European Medicines Agency, London, UK

Course Directors

European Medicines Agency representatives invited

Gaby Danan
Pharmacovigilance Expert
France

Faculty

Barry Arnold
EU Qualified Person for Pharmacovigilance
AstraZeneca, UK

European Medicines Agency representatives invited

William Gregory
Director, Safety and Risk Management
Pfizer, USA

Jan Petracek
CEO
PharmInvent, Czech Republic

Nick Phillips
Head of Inspections Management, PDQA
Roche Products Ltd., UK

Patrice Verpillat
Head of Department, International Epidemiology Dept.,
H. Lundbeck A/S, France

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

Overview

This course is designed to provide a firm grounding in key aspects of Global Clinical Pre and Post Marketing Safety. This five-day training course, presented by the European Medicines Agency, is now also including highlights and updates on the implementation of the new pharmacovigilance legislation and the latest news on the international harmonisation and standardisation activities in pharmacovigilance.

Who Will Attend

Professionals involved in pharmacovigilance, clinical research, regulatory affairs, risk management, medical product safety assessment, and data analysis, epidemiology, labelling, quality assurance, compliance, medical information.

Level: Intermediate

Learning Objectives

For the five key topics as outlined below, the learning objectives now also include the ability to:
- Describe the main changes to the business processes in the context of the new pharmacovigilance legislation
- Discuss the latest developments in the area of international harmonisation and standardisation with main focus on the ICH E2B, E2C, E2F topics and the ISO Individual Case Safety Report (ICSR) and Identification of Medicinal Products (IDMP) standards

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

Definitions and Methods in Pharmacovigilance
- Describe the scope and objectives of Pharmacovigilance and Risk Management and the relationship between the two concepts
- Discuss the development of definitions based on legislation and consensus fora
- Identify the key definitions and the vocabulary used in Pharmacovigilance in the European Union, illustrated by practical examples and exercises

Regulatory Aspects in Pharmacovigilance and Practical Examples
- Describe the European regulatory requirements in Pharmacovigilance
- Describe the requirements of establishing a Pharmacovigilance database and the use of the Medical Dictionary for Regulatory Activities (MedDRA) including the key functionalities of EudraVigilance
- Discuss the Pharmacovigilance System Master File and the preparation for audits and inspections

Diagnosis and Management of Adverse Drug Reactions
- Discuss the key elements of the medical evaluation of adverse events
- Recognise the important aspects in evaluating adverse events based on two examples
- Identify the main characteristics of drug induced adverse events

Signal Detection
- Understand MedDRA dictionary
- Describe signal detection and management in the EU based on GVP module IX

Risk Management
- Explain the EU risk management strategy, the new approaches to risk assessment and prevention, and the different steps to be considered in the risk management process
- Describe the components of the GVP module V on the risk management systems
- Define the concept of risk, and explain differences between individual and population risks
- Explain and illustrate methods used in pharmacoepidemiology for measuring risks and estimating their association with drug exposure
- Describe current recommendations and practices of benefit-risk assessment, post-authorisation efficacy studies and post-authorisation safety studies
- Understand the main principles of risk communication based on case studies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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MONDAY | 18 FEBRUARY 2013

08:00 REGISTRATION

08:45 Keynote Presentation

THE ROLE OF THE EUROPEAN MEDICINES AGENCY IN PHARMACOVIGILANCE

European Medicines Agency representative invited

09:45 TOPIC 1

DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

Overview of Topic 1

Topic 1 will provide a concise overview of the objectives and the scope of Pharmacovigilance and Risk Management and the relationship between the two concepts. The development of key definitions based on Community legislation and consensus fora such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the CIOMS Working Groups will be summarised. Practical examples and exercises will be used to illustrate the key definitions and vocabulary applied in Pharmacovigilance.

09:45 Topic 1 Session 1

BASIC DEFINITIONS AND TOOLS INCLUDING ICH GUIDELINES AND CIOMS RECOMMENDATIONS

European Medicines Agency representative invited

Gaby Danan, Pharmacovigilance Expert, France

10:45 COFFEE BREAK

11:15 Topic 1 Session 1 continued

BASIC DEFINITIONS AND TOOLS INCLUDING ICH GUIDELINES AND CIOMS RECOMMENDATIONS

European Medicines Agency representative invited

Gaby Danan, Pharmacovigilance Expert, France

13:15 LUNCH

14:15 Topic 1 Session 2

CLASSICAL METHODS IN PHARMACOVIGILANCE

Gaby Danan, Pharmacovigilance Expert, France

16:00 COFFEE BREAK

16:30 TOPIC 2

REGULATORY ASPECTS IN PHARMACOVIGILANCE AND PRACTICAL EXAMPLES

Overview of Topic 2

The roles and responsibilities of marketing authorisation holders and national Competent Authorities in the conduct of Pharmacovigilance are defined in EU legislation and further detailed in the Good Pharmacovigilance Practices (GVP). Topic 2 will provide a concise summary of the adverse reaction reporting requirements of marketing authorisation holders in the post-authorisation phase and illustrations based on practical case studies.

Furthermore, the roles and responsibilities of all stakeholders of interventional clinical trials in line with the implementing texts published in relation to Directive 2001/20/EC are summarised.

Aspects that need to be taken into account in establishing a Pharmacovigilance database as well as the key functionalities of the EU's EudraVigilance system will be discussed.

The main elements will be provided for the establishment of a quality system in Pharmacovigilance including aspects of the applicable GVP modules, the elaboration of Standard Operating Procedures (SOPs) and the preparation for audits and inspections.

16:30 Topic 2 Session 1

SUSAR REPORTING IN INTERVENTIONAL CLINICAL TRIALS AND CASE STUDIES

European Medicines Agency representative invited

Gaby Danan, Pharmacovigilance Expert, France

18:00 DRINKS RECEPTION

19:00 END OF DAY ONE

TUESDAY | 19 FEBRUARY 2013

08:30 Topic 2 Session 1 continued

SUSAR REPORTING IN INTERVENTIONAL CLINICAL TRIALS AND CASE STUDIES

European Medicines Agency representative invited

Gaby Danan, Pharmacovigilance Expert, France

10:00 COFFEE BREAK

10:30 Topic 2 Session 2

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES

European Medicines Agency representative invited

William Gregory, Pfizer, USA

12:00 LUNCH

13:00 Topic 2 Session 2 continued

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES

European Medicines Agency representative invited

William Gregory, Pfizer, USA

14:45 COFFEE BREAK

15:15 Topic 2 Session 2 continued

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES

European Medicines Agency representative invited

William Gregory, Pfizer, USA

17:15 END OF DAY TWO

WEDNESDAY | 20 FEBRUARY 2013

08:30 Topic 2 Session 3

REPORTING REQUIREMENTS IN SPECIAL SITUATIONS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES

William Gregory, Pfizer, USA

10:00 COFFEE BREAK

10:30 Topic 2 Session 4

PREPARATION OF ANNUAL SAFETY REPORTS (ASRs) / DEVELOPMENT SAFETY UPDATE REPORTS (DSURs)

Barry Arnold, AstraZeneca, UK

11:15 Topic 2 Session 5

PREPARATION OF PERIODIC SAFETY UPDATE REPORTS (PSURs)

Barry Arnold, AstraZeneca, UK

12:30 LUNCH

13:30 Topic 2 Session 6

THE ROLE OF THE QUALIFIED PERSON RESPONSIBLE FOR PHARMACOVIGILANCE
Barry Arnold, AstraZeneca, UK

14:15 Topic 2 Session 7

DETAILED DESCRIPTION OF THE PHARMACOVIGILANCE SYSTEM
European Medicines Agency representative invited

15:15 COFFEE BREAK

15:30 Topic 2 Session 7 continued

DETAILED DESCRIPTION OF THE PHARMACOVIGILANCE SYSTEM
European Medicines Agency representative invited

16:30 COFFEE BREAK

16:45 Topic 2 Session 7 continued

AUDITS AND INSPECTIONS IN PHARMACOVIGILANCE
Nick Phillips, Roche Products Ltd., UK

18:15 END OF DAY THREE

THURSDAY | 21 FEBRUARY 2013

08:30 TOPIC 3

DIAGNOSIS AND MANAGEMENT OF ADVERSE DRUG REACTIONS
Overview of Topic 3

Pharmacovigilance is first based on the medical assessment of the adverse events passively or actively collected in organised schemes. It is then essential to be able to identify consistently the nature of events, their seriousness, their expectedness and to assess causality with the suspect drug(s). This session will provide clues for the recognition of two serious events involving target organs of drug toxicity.

08:30 Topic 3 Session 1

MEDICAL EVALUATION OF ADVERSE DRUG REACTIONS
Gaby Danan, Pharmacovigilance Expert, France

09:30 Topic 3 Session 2

DRUG-INDUCED LIVER INJURY
Gaby Danan, Pharmacovigilance Expert, France

10:30 COFFEE BREAK

11:00 Topic 3 Session 2 continued

DRUG-INDUCED LIVER INJURY
Gaby Danan, Pharmacovigilance Expert, France

11:30 Topic 3 Session 3

QT/QTC PROLONGATION AND THE RISK OF TORSADE DE POINTES
Gaby Danan, Pharmacovigilance Expert, France

12:30 LUNCH

13:30 TOPIC 4

SIGNAL DETECTION
Overview of Topic 4

New safety signals may emerge at any time following product launch and must be evaluated for relative risk, medical importance, and likelihood of occurrence. This session will provide an understanding of safety data classification, using MedDRA terminology and Standardised MedDRA Queries (SMQs) and approaches to signal detection using traditional and quantitative methods.

13:30 Topic 4 Session 1

MedDRA AND STANDARDISED MedDRA QUERIES (SMQs)
William Gregory, Pfizer, USA

14:15 Topic 4 Session 2

INTRODUCTION TO SIGNAL DETECTION
European Medicines Agency representative invited

15:00 COFFEE BREAK

15:30 Topic 4 Session 3

SIGNAL MANAGEMENT IN THE EUROPEAN UNION
- Regulatory Network Perspective
  European Medicines Agency representative invited
- Industry Perspective
  Jan Petracek, PharmInvent, Czech Republic

16:30 TOPIC 5

RISK MANAGEMENT
Overview of Topic 5

In accordance with the GVP Module V on Risk Management System, risk management plans (RMPs) should be submitted by companies to propose activities aiming to identify, characterise or minimise risks associated with medicinal products. Given the potential public health implications and costs of such interventions, RMPs should be based on robust epidemiological methods.

This session aims to provide the background for understanding drug-related risks, to review epidemiological methods for detecting signals and assessing risks, and to present recent developments regarding risk communication.

16:30 Topic 5 Session 1

RISK COMMUNICATION IN EU - CHALLENGES AND POSSIBILITIES
Jan Petracek, PharmInvent, Czech Republic

18:00 END OF DAY FOUR

FRIDAY | 22 FEBRUARY 2013

08:30 Topic 5 Session 2

RISK MANAGEMENT COMPONENTS: GENERAL PRINCIPLES
European Medicines Agency representative invited

09:45 Topic 5 Session 3

RISK MANAGEMENT PLANS: AN INDUSTRY PERSPECTIVE
Patrice Verpillat, H. Lundbeck A/S, France

10:45 COFFEE BREAK

11:15 Topic 5 Session 4

POST-AUTHORISATION DEVELOPMENT PLAN (PASS/PAES)
European Medicines Agency representative invited

11:45 Topic 5 Session 5

EPIDEMIOLOGICAL METHODS AND PHARMACOVIGILANCE
Patrice Verpillat, H. Lundbeck A/S, France

12:45 LUNCH

13:45 Topic 5 Session 5 continued

EPIDEMIOLOGICAL METHODS AND PHARMACOVIGILANCE
Patrice Verpillat, H. Lundbeck A/S, France

14:45 Topic 5 Session 6

EFFECTIVENESS OF RISK MINIMISATION MEASURES
Jan Petracek, PharmInvent, Czech Republic

15:30 END OF TRAINING COURSE

REGISTRATION FORM

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ID #13502

DIA www.diahome.org

If DIA cannot verify your membership upon receipt of the 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, and might be subject to local UK VAT.

CATEGORY	Member Fee	Non-Member Fee
Industry	€ 2'961.00 ❑	€ 3'076.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 1'481.00 ❑	€ 1'596.00 ❑

Join DIA now to qualify for the member rate — Fee € 115.00 ❑

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION

ATTENDEE DETAILS

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

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ 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

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ 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 #13502 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.

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
Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you 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 registered attendees. Registered attendees 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 attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

HOTEL INFORMATION

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

Hilton London Docklands Riverside
265 Rotherhithe Street
SE16 5HW London
UK
Tel.: +44 20 7231 1001
Fax: +44 20 7231 0599

Email: reservations.docklands@hilton.com
Website: www.hilton.co.uk/docklands

at the rate of:

GBP 149.00 per single room and GBP 159.00
per double room inclusive of breakfast, exclusive of VAT.

To make your reservation please use the following link:
http://www.hilton.com/en/hi/groups/personalized/L/LONNDHI-GDIAE-20130217/index.jhtml?WT.mc_id=POG

If cancellation occurs within 7 days of arrival, a 100% cancellation charge of one night stay will apply.

IMPORTANT: Please complete your reservation by Friday, **4 January 2013**. Reservations received after this date will be subject to hotel availability and room rate may vary.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe 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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