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

Course #14500
17-21 February 2014
European Medicines Agency, 7 Westferry Circus,
Canary Wharf, London, E14 4HB, UK

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Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 25 CPD credits.

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 35 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, now also includes 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 the 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 Good Pharmacovigilance Practices (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

DIA®

MONDAY | 17 FEBRUARY 2014

08:00 REGISTRATION

08:45 Keynote Presentation

THE ROLE OF THE EUROPEAN MEDICINES AGENCY IN PHARMACOVIGILANCE
Sabine Brosch, European Medicines Agency, EU

09:45 TOPIC 1

DEFINITIONS AND METHODS IN PHARMACOVIGILANCE

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
Sabine Brosch, European Medicines Agency, EU
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
Sabine Brosch, European Medicines Agency, EU
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

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
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

18:00 DRINKS RECEPTION

19:00 END OF DAY ONE

TUESDAY | 18 FEBRUARY 2014

08:30 Topic 2 Session 1 continued

SUSAR REPORTING IN INTERVENTIONAL CLINICAL TRIALS AND CASE STUDIES
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

10:00 COFFEE BREAK

10:30 Topic 2 Session 2

PREPARATION OF ANNUAL SAFETY REPORTS (ASRs) / DEVELOPMENT SAFETY UPDATE REPORTS (DSURs)
Barry Arnold, AstraZeneca, UK

11:15 Topic 2 Session 3

PREPARATION OF PERIODIC SAFETY UPDATE REPORTS (PSURs)
Barry Arnold, AstraZeneca, UK

12:30 LUNCH

13:30 Topic 2 Session 4

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

14:15 Topic 2 Session 5

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

15:45 COFFEE BREAK

16:15 Topic 2 Session 5 continued

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

18:00 END OF DAY TWO

WEDNESDAY | 19 FEBRUARY 2014

08:30 Topic 2 Session 5 continued

EXPEDITED REPORTING REQUIREMENTS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES
Sabine Brosch, European Medicines Agency, EU
Gaby Danan, Pharmacovigilance Expert, France

10:30 COFFEE BREAK

11:00 Topic 2 Session 6

REPORTING REQUIREMENTS IN SPECIAL SITUATIONS IN THE POST-AUTHORISATION PHASE AND CASE STUDIES
William Gregory, Pfizer, USA

12:30 LUNCH

13:30 Topic 2 Session 7

DETAILED DESCRIPTION OF THE PHARMACOVIGILANCE SYSTEM
Sabine Brosch, European Medicines Agency, EU

14:30 COFFEE BREAK

14:45 Topic 2 Session 7 continued

DETAILED DESCRIPTION OF THE PHARMACOVIGILANCE SYSTEM
Sabine Brosch, European Medicines Agency, EU

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15:45 COFFEE BREAK

16:00 Topic 2 Session 7 continued

AUDITS AND INSPECTIONS IN PHARMACOVIGILANCE
Terry Faulkner, Johnson & Johnson, UK

17:30 END OF DAY THREE

THURSDAY | 20 FEBRUARY 2014

08:30 TOPIC 3

DIAGNOSIS AND MANAGEMENT OF ADVERSE DRUG REACTIONS

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 likelihood of occurrence 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

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
Georgy Genov, European Medicines Agency, EU

15:00 COFFEE BREAK

15:30 Topic 4 Session 3

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

16:30 TOPIC 5

RISK MANAGEMENT

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 | 21 FEBRUARY 2014

08:30 Topic 5 Session 2

RISK MANAGEMENT COMPONENTS: GENERAL PRINCIPLES
Thomas Goedecke, European Medicines Agency, EU

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)
Xavier Kurz, European Medicines Agency, EU

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

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
United Kingdom

Tel.: +44 207 231 1001
Fax: +44 207 231 0599
Email: reservations.docklands@hilton.com
Website: www.hilton.co.uk/docklands

at the rate of:
GBP 139.00 per single room and **GBP 149.00** per double room inclusive of breakfast and VAT.

To make your reservation, please use the booking link available on the DIA website. If cancellation occurs within 7 days of arrival, a 100% cancellation charge of one night stay will apply.

IMPORTANT: The room rate is available until 6 January 2014 or until the group block is sold-out, whichever comes first.

REGISTRATION FORM

EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing training course
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DIA www.diahome.org
ID #14500

FEES

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

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

Registration fee includes: refreshments, lunches and training course material.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

TOTAL AMOUNT DUE: _____

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Course ID # 14500 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00
- Tutorial cancellation € 50.00

If you do not cancel five working days prior to the event 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 or postponed, 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.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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