Introduction to Signal Detection and Data Mining in Pharmacovigilance

Course #12555
7-8 May 2012
Novotel Berlin Mitte, Berlin, Germany

Course Faculty

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Former Head of Risk Management, European Medicines Agency, EU

About the DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications at a reasonable, competitive cost.

DIA’s headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

This course has limited capacity. Register early.

Course Overview

The World Health Organisation (WHO) defines the term Signal as “reported information on a possible causal relationship between an adverse event and drug, the relationship being unknown or incompletely documented previously”. Adverse Drug Reactions (ADRs) may be identified as Signals for clinical and/or quantitative reasons. This course will cover the fundamentals of classical and statistical signal detection and data mining in Pharmacovigilance.

Who Will Attend

Professionals who work in:
• Pharmacovigilance (including QPPV)
• Clinical Development
• Risk Management
• Pharmacoepidemiology
• Information Technology
• Regulatory Affairs
• Quality and Compliance
• Legal

Course Level

For professionals with 2-3 years of experience in pharmacovigilance this course will be at a beginner level; professionals from other areas, or with less experience, will find this course more advanced.

Learning Objectives

At the conclusion of this course, participants should be able to:
• Explain and apply the basic concepts and principles of signal detection in Pharmacovigilance
• Explain the role and differences of classical and statistical signal detection in the ongoing safety surveillance of medicinal products
• Outline how to apply signal detection within their function based on the possibilities and limitations of methodology and data
• Employ data mining techniques to analyse large volumes of adverse event report data
• Discuss key messages from the EMA Guideline on the uses of statistical signal detection methods in the Eudravigilance Data Analysis System

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 9 credits.
AGENDA

Day 1
9:30 Registration
10:00 Training course sessions
12:00 Lunch
13:00 Training course sessions
15:00 Coffee break
15:30 Training course sessions
17:30 End of day 1

Day 2
8:30 Training course sessions
10:00 Coffee break
10:30 Training course sessions
12:00 End of training course

Session 1
Signal Detection – Theory, Methods and Regulatory Basis

Session 2
Signal Detection – Application and Workshop

Session 3
Data Mining – Theory, Methods

Session 4
Data Mining – Application

Hotel Information

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

Novotel Berlin Mitte
Fischerinstel 12
D-10179 Berlin

Email: H3278-sb1@accor.com
Tel: 0049 30 20674 114
Fax: 0049 30 20674111
Website: http://www.novotel.com/de/hotel-3278-novotel-berlin-mitte/index.shtml

at the special rate of:
EUR 109.00 per standard room, single occupancy inclusive of breakfast buffet and VAT
EUR 126.00 per standard room, double occupancy inclusive of breakfast buffet and VAT

To make your reservation please contact the hotel directly by using the hotel booking form available on our website.

Important:
Please complete your reservation by 5 April 2012. Reservations received after this date will be subject to hotel availability and room rate may vary.

Cancellation:
Cancellations of reservations are possible until 48 hours prior to arrival. Any cancellation made less than 48 hours prior to arrival will be charged for the entire length of stay. No shows will be billed for the entire stay.

Unless otherwise disclosed, DIA Europe 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 Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.
DIA UPCOMING TRAINING COURSES IN 2012

Chemistry, Manufacturing and Controls (CMC) / Quality

- Chemistry, Manufacturing & Controls (CMC)
  08-10 May 2012 | Vienna, Austria | ID 12579

- CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
  26-27 April 2012 | Istanbul, Turkey | ID 12557

- Quality by Design: New Concepts for Development & Manufacturing - A hands-on course for pharma
  September 2012 | Location to be confirmed | ID 12573

Clinical Research

- Advanced GCP Study Monitoring
  Autumn 2012 | Location to be confirmed | ID 12585

- Clinical Project Management – Part I
  November 2012 | Location to be confirmed | ID 12572

- Clinical Project Management – Part II
  22-24 February 2012 | Nice, France | ID 12554

- Clinical Statistics for Non-Statisticians
  25-26 October 2012 | Location to be confirmed | ID 12567

- Essentials of Clinical Study Management
  23-25 May 2012 | Munich, Germany | ID 12560
  14-16 November 2012 | Paris, France | ID 12570

- Practical GCP Compliance Auditing of Trials and Systems
  17-19 October 2012 | London, United Kingdom | ID 12568

- Quality Risk Management (QRM)
  25 March 2012 | Copenhagen, Denmark | ID 12584

Non-Clinical Sciences

- Non-Clinical Safety Sciences and Their Regulatory Aspects
  19-23 November 2012 | Lisbon, Portugal | ID 12571

Regulatory Affairs

- Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe
  21-23 May 2012 | Basel, Switzerland | ID 12559

- Building the eCTD - Practical solutions to compile electronic submissions
  8-9 March 2012 | Barcelona, Spain | ID 12564
  October 2012 | Berlin, Germany | ID 12577

- Comprehensive Training on European Regulatory Affairs: Keeping your finger on the pulse of Marketing Authorisation
  Autumn 2012 | Location to be confirmed | ID 12563

- European Regulatory Affairs: In-depth review of current registration procedures in the European Union
  16-17 February 2012 | Vienna, Austria | ID 12553
  14-15 June 2012 | Berlin, Germany | ID 12583
  15-16 November 2012 | Paris, France | ID 12569

- Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects as used in personalised medicine
  November 2012 | Location to be confirmed | ID 12576

- Health Authority Interactions
  September 2012 | Location to be confirmed

- Health Technology Assessment (HTA)
  Date to be confirmed | Location to be confirmed | ID 12578

- Paediatric Investigation Plans (PIP)
  23-24 April 2012 | Amsterdam, The Netherlands | ID 12580

- US Regulatory Affairs: A Comprehensive Review of Regulatory Procedures for INDs and NDAs in the US
  5-7 November 2012 | Paris, France | ID 12586

Safety and Pharmacovigilance

- Benefit/Risk Management
  24-25 May 2012 | Munich, Germany | ID 12561

- EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing
  15-17 February 2012 | London, United Kingdom | ID 12551
  1-5 October 2012 | Prague, Czech Republic | ID 12566

- EudraVigilance Information Day at the European Medicines Agency
  27 April 2012 | London, United Kingdom | ID 12533
  21 September 2012 | London, United Kingdom | ID 12534

- How to Prepare for Pharmacovigilance Audits and Inspections
  8-9 May 2012 | Berlin, Germany | ID 12556
  November 2012 | Location to be confirmed | ID 12575

- IDMP Information Day at the European Medicines Agency
  8 May 2012 | London, United Kingdom | ID 12537
  4 December 2012 | London, United Kingdom | ID 12536

- Information Day on the Implementation of Electronic Submission of Medical Product Information in the EU at the European Medicines Agency
  21 February 2012 | London, United Kingdom | ID 12561

- ICSR Information Day at the European Medicines Agency
  Date to be confirmed | London, United Kingdom | ID 12535

- Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
  17 April 2012 | London, United Kingdom | ID 12538
  16 October 2012 | London, United Kingdom | ID 12539
  20 November 2012 | London, United Kingdom | ID 12540

- Introduction to Signal Detection and Data Mining in Pharmacovigilance
  7-8 May 2012 | Berlin, Germany | ID 12555
  November 2012 | Location to be confirmed | ID 12574

- Medical Approach in Diagnosis and Management of ADRs
  15-16 October 2012 | Paris, France | ID 12565

- Practical Guide for Pharmacovigilance: Clinical trials and post-marketing
  21-23 May 2012 | Berlin, Germany | ID 12562

- Pre-Marketing Clinical Safety
  26-27 April 2012 | Prague, Czech Republic | ID 12558

- EudraVigilance (EV) and Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)
  Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
  For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

In-house Training Courses

In-house training is a highly flexible, efficient and cost-effective way to get the maximum return on your training investment. In-house courses are available to all stakeholders, both public and private institutions.

Contact DIA Europe to discuss your organisation’s requirements.
REGISTRATION FORM
Introduction to Signal Detection and Data Mining in Pharmacovigilance
7-8 May 2012 | Novotel Berlin Mitte, Berlin, Germany

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. * All fees are subject to local German VAT of 19%

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

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

P | Clinical Data Management, eClinical | Non-clinical, Outsourcing
P | Clinical Research & Development | Comparative Effectiveness/Health Technology
P | Clinical Safety/Pharmacovigilance | Assessment/
P | Document Management, eSubmissions | Evidence-based Medicine
P | Medical Communications | Pricing/Reimbursement
S | Medical Writing | Professional Education & Training
S | Government | Public Policy/Law
S | Industry | Quality Assurance/Quality Control
S | Contract Service Organisation | Regulatory Affairs
S | Evidence-based Medicine | Statistics
S | Pricing/Reimbursement | IT/Validation
S | Professional Education & Training | Public Policy/Law
S | Contract Service Organisation | Regulatory Affairs
S | Evidence-based Medicine | IT/Validation

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

Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Kuechengasse 16, Postfach, 4002 Basel, Switzerland

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# 12555 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
Regrettably, 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.

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.

Online www.diahome.org Fax +41 61 225 51 52
Email diaeurope@diaeurope.org Mail DIA Europe Postfach, 4002 Basel, Switzerland

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