Introduction to Signal Detection and Data Mining in Pharmacovigilance

Course #11569
8-9 November 2011
nhow Hotel, Berlin, Germany

Course Faculty

Thomas Steinbach
Former Qualified Person for Pharmacovigilance, Pharmacovigilance Expert, London, United Kingdom

About the Drug Information Association

The DIA is a professional association of approximately 18,000 members worldwide who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. We are committed to the broad dissemination of information on the development of new medicines or generics and biosimilars, with continuously improved professional practice as the goal. The DIA is a financially independent non-profit organisation that funds itself from meeting and membership fees. 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.

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

13:30  Registration
14:00  Training course sessions
15:30  Coffee break
16:00  Training course sessions
18:00  End of day 1

Day 2

08:30  Training course sessions
10:30  Coffee break
11:00  Training course sessions
13:00  Lunch
14:00  Training course sessions
15:30  End of training course

Hotel Information

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

nhow Berlin
Stralauer Allee 3
10246 Berlin
Tel: +49 30 290 299 – 4005
Fax: +49 30 290 299 – 2000
Email: h.wieck@nhow-hotels.com

at the special rate of EUR 150.00 per room/day excluding breakfast of € 22 per person/day.

To reserve a room, please contact the hotel directly.

IMPORTANT
To be assured of accommodation at the hotel, registrants are recommended to complete their reservation by 22 September 2011. Reservations received after this date is subject to availability.

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.

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

DIA ConneX You
DIA’s new members-only social networking-style website is a vital resource for professionals like you looking to connect with others in your field and improve your job performance.

How Can DIA ConneX Help You?
• Get answers to on-the-job questions
• Access shared resources such as white papers and articles
• Network with thousands of your colleagues worldwide

Get connected at www.diahome.org/DIAConneX.
**Clinical Research**

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<tr>
<th>Course</th>
<th>Date</th>
<th>Location</th>
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<tr>
<td>Advanced GCP Study Monitoring</td>
<td>19 September 2011</td>
<td>Paris, France</td>
<td>11531</td>
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<tr>
<td>Clinical Project Management – Part I</td>
<td>21-23 November 2011</td>
<td>Vienna, Austria</td>
<td>11528</td>
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<tr>
<td>Clinical Statistics for Non-Statisticians</td>
<td>6-7 October 2011</td>
<td>Vienna, Austria</td>
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<td>Essentials of Clinical Study Management</td>
<td>2-4 November 2011</td>
<td>Paris, France</td>
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<tr>
<td>Practical GCP Compliance Auditing of Trials &amp; Systems</td>
<td>26-28 October 2011</td>
<td>London, UK</td>
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**Safety and Pharmacovigilance**

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<tr>
<td>Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing</td>
<td>3-7 October 2011</td>
<td>Zagreb, Croatia</td>
<td>11548</td>
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<tr>
<td>How to Prepare for Pharmacovigilance Audits and Inspections</td>
<td>7-8 November 2011</td>
<td>Berlin, Germany</td>
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<td>Introduction to Signal Detection and Data Mining in Pharmacovigilance</td>
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<td>Berlin, Germany</td>
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<td>Medical Approach in Diagnosis and Management of ADRs</td>
<td>19-20 September 2011</td>
<td>Paris, France</td>
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<td>EudraVigilance Information Day at the European Medicines Agency</td>
<td>15 November 2011</td>
<td>London, UK</td>
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<td>IDMP Information Day at the European Medicines Agency</td>
<td>22-23 September 2011</td>
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<td>ICSR Information Day at the European Medicines Agency</td>
<td>16 November 2011</td>
<td>London, UK</td>
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<td>ICSR Technical Implementation Training at the European Medicines Agency</td>
<td>17 November 2011</td>
<td>London, UK</td>
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<td>Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of EudraVigilance at the European Medicines Agency</td>
<td>13 September 2011</td>
<td>London, UK</td>
<td>11552</td>
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<td>EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)</td>
<td>Courses throughout the year</td>
<td>European Medicines Agency, London, United Kingdom and selected European cities. For course details on EV, please visit <a href="http://www.diahome.org">www.diahome.org</a> &gt; Training &gt; EudraVigilance &gt; Click on &gt; Related Courses</td>
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**Regulatory Affairs**

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<tr>
<td>Building the eCTD - Practical Solutions to Compile Electronic Submissions</td>
<td>6-7 October 2011</td>
<td>Vienna, Austria</td>
<td>11529</td>
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<td>CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3</td>
<td>27-29 November 2011</td>
<td>Abu Dhabi, UAE</td>
<td>11533</td>
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<td>eCTD Submissions in Switzerland</td>
<td>8 December 2011</td>
<td>Zurich, Switzerland</td>
<td>11590</td>
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<tr>
<td>European Regulatory Affairs: In-depth Review of Current Registration Procedures in the European Union</td>
<td>3-4 November 2011</td>
<td>Paris, France</td>
<td>11546</td>
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<tr>
<td>Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and Practical Aspects as used in Personalised Medicine</td>
<td>14-17 November 2011</td>
<td>Zurich, Switzerland</td>
<td>11568</td>
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<td>Quality by Design: New Concepts for Development &amp; Manufacturing - A Hands-on Course for Pharma</td>
<td>3-4 November 2011</td>
<td>Vienna, Austria</td>
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**Non-Clinical Sciences**

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<tr>
<td>Non-Clinical Safety Sciences and Their Regulatory Aspects</td>
<td>21-25 November 2011</td>
<td>Lisbon, Portugal</td>
<td>11567</td>
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For more information and a complete listing of all training courses, please visit [www.diahome.org](http://www.diahome.org) and click on Training.
REGISTRATION FORM

Introduction to Signal Detection and Data Mining in Pharmacovigilance
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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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<tr>
<th>CATEGORY</th>
<th>Member Fee</th>
<th>Non-Member Fee</th>
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<tr>
<td>Industry</td>
<td>€ 1'155.00</td>
<td>€ 1'270.00</td>
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<tr>
<td>Government /Charitable/Non-profit/Academia (Full-Time)</td>
<td>€ 578.00</td>
<td>€ 693.00</td>
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Join DIA now to qualify for the member rate

TOTAL AMOUNT DUE: €__________

NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

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.

__ CMC __ Clinical Data Management/ eClinical
__ Clinical Research & Development __ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Medical Communications
__ Medical Writing __ Non-clinical __ Outsourcing
__ Comparative Effectiveness/Health Technology __ Assessment/
__ Evidence-based Medicine __ Pricing/Reimbursement __ Project Management
__ Professional Education & Training __ Public Policy/Law
__ Quality Assurance/Quality Control __ Regulatory Affairs
__ Statistics __ 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
- Date
- Cardholder’s Signature
- Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Elisabethenanlage 25, 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# 11569 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

Regrettfully, 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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