# Course Overview

This one day course is designed for newcomers in pharmacovigilance, in particular individuals dedicated to data entry and quality review of ICSRs. The attendees will learn about the essentials of pharmacovigilance, the format, structure and content of ICSRs as well as data quality and coding principles, which are prerequisites to comply with EU and international reporting requirements. This introductory course is strongly recommended to individuals that will be transmitting ICSRs to EudraVigilance.

## Key Topics

- Legal/regulatory basis
- Compliance with reporting requirements for ICSRs
- What is a pharmacovigilance case: scope, criteria for validity
- Classification of cases: Solicited/ unsolicited, serious/not serious, etc
- Overview of the ICH E2B requirements
- Main differences of data elements and adverse reaction reporting during clinical trials and in the post-authorisation phase
- Overview of the case flow in the EU
- Concepts and data elements of an ICSR (the main part of the training, focusing on content and quality criteria of each important element)
- Case Follow-up: when and how it needs to be transmitted.
- Basic coding principles
- Data privacy requirements

## Course Goals

This course is intended to prepare newcomers for the 3-day EudraVigilance training course. At the conclusion of this course, participants should be able to:

- Understand the ICSR reporting requirements
- Understand the basic vocabulary of pharmacovigilance
- Complete properly the components of an ICSR
- Compare ICSR components for post-authorisation and clinical trials
- Identify the resources available for further guidance

## Course Audience

This course is intended for newcomers in pharmacovigilance, who need to understand the basics of ICSRs with main focus on EU requirements.
COURSE AGENDA

09:00  Course Introduction
  Session 1  Pharmacovigilance background and regulatory framework
  Session 2  Key concepts and definitions

11:15  COFFEE BREAK
11:30  Exercises on session 2
  Session 3  Reporting requirements for expedited ICSR

13:00  LUNCH

14:00  Exercises on session 3
  Session 4  Requirements for data quality in ICSRs

15:45  COFFEE BREAK
16:00  Session 5  Coding, MedDRA
  Session 6  Data privacy protection

17:30  END OF DAY

Upcoming Courses in Safety and PharmacoVigilance

Benefit/Risk Management  
19-20 May 2011 | Prague, Czech Republic | ID 11562

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing  
21-25 February 2011 | EMA, London, United Kingdom | ID 11549
3-7 October 2011 | Zagreb, Croatia | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections  
10-11 May 2011 | Amsterdam, The Netherlands | ID 11542
November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance  
9-10 May 2011 | Amsterdam, The Netherlands | ID 11543
November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs  
19-20 September 2011 | Paris, France | ID 11530

Practical Guide for Pharmacovigilance: Clinical Trials and Post-Marketing  
16-18 May 2011 | Nice, France | ID 11527

Pre-marketing Clinical Safety  
4 April 2011 | Basel, Switzerland | ID 11565

DSURs Information Day at the European Medicines Agency  
23 March 2011 | London, United Kingdom | ID 11579

EudraVigilance Information Day at the European Medicines Agency  
10 May 2011 | London, United Kingdom | ID 11520
15 November 2011 | London, United Kingdom | ID 11522

IDMP Information Day at the European Medicines Agency  
16 September 2011 | London, United Kingdom | ID 11524

ICSR Information Day at the European Medicines Agency  
5 April 2011 | London, United Kingdom | ID 11523
16 November 2011 | London, United Kingdom | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency  
17 November 2011 | London, United Kingdom | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency  
8 February 2011 | London, United Kingdom | ID 11550
7 June 2011 | London, United Kingdom | ID 11551
13 September 2011 | London, United Kingdom | ID 11552
6 December 2011 | London, United Kingdom | ID 11553

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPO)  
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

Hotel and Travel Information

Recommended hotels nearby the EMA  
Attendees must make their own hotel reservation  
Ask for available EMA rate at:

Hilton London Docklands Riverside  
265 Rotherhithe Street, London , SE16 5HW, UK  
Telephone: +44 (0)20 7231 1001  
Fax: +44 (0)20 7231 0599  
Email: reservations.docklands@hilton.com

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 DIA Europe.

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.
Registrations will be accepted by fax or email. Each course is limited to 16 participants. The registration fee includes training course material, IT equipment and refreshments. The course may be cancelled if numbers of participants are not sufficient.

### REGISTRANT

Please complete in block capital letters or make registration even simpler by attaching the registrant'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 (Required to receive presentation download instructions)

Please indicate your professional category:
- Academia
- Industry
- Contract Service Organisation

### PAYMENT METHODS - Credit cards are our 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
Exp. 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 to facilitate identification to: DIA, 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# 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.

### STANDARD FEES

- **Standard fee**: € 600.00
- **Reduced Fee for Academia and Full Government**: € 300.00

SPECIAL DISCOUNT FOR SME (STATUS CONFIRMED BY EMA) AVAILABLE. MULTIPLE COURSE DISCOUNT AVAILABLE IF BOOKED TOGETHER WITH THE THREE DAY EUDRAVIGILANCE TRAINING COURSE. PLEASE CONTACT THE DIA FOR MORE INFORMATION.

### 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.

Full Meeting Cancellation: Industry (Member/non-member) = € 200.00. Government/Academia/Non-profit (Member/non-member) = € 100.00. Registered attendees who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registered attendees are responsible for cancelling their own hotel reservations. 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.

### 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 office of any such substitutions as soon as possible.

### 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.

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

© DIA 2010