Introduction

EudraVigilance is the European data-processing network and management system, established at the European Medicines Agency to support the electronic exchange, management and scientific evaluation of Individual Case Safety Reports (ICSRs) related to all medicinal products authorised in the European Economic Area (EEA).

EudraVigilance also incorporates signal detection and data analysis facilities and is therefore regarded as one of the main pillars of the European Risk Management Strategy, which aims to strengthen the conduct of pharmacovigilance in the EEA.

Community legislation is in place to ensure that all stakeholders, including National Competent Authorities (NCAs), marketing authorisation holders (MAHs) and sponsors of clinical trials in the EEA collect, collate and exchange adverse drug reactions.

The electronic transmission of ICSRs, based on the results of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) remains a priority in the area of pharmacovigilance to make the adverse reaction data exchange and management more efficient.

EVWEB is an Internet-based reporting tool developed by the European Medicines Agency to allow Small and Medium Size Enterprises (SMEs) that hold marketing authorisations in the EEA and sponsors of clinical trials, to report electronically adverse reactions, in full compliance with the internationally agreed standards to the European Medicines Agency and NCAs.

The EudraVigilance Training Programme has been designed for:

- Organisations e.g. SMEs, (non-) commercial sponsors that intend to use EVWEB to implement electronic transmission of safety data. Organisations intending to use EVWEB are required to follow a training course to ensure the correct use of the reporting tool. They can apply for more than one person to be trained, or alternatively, send one person who will subsequently train other users internally in the organisation.

- Pharmaceutical companies that perform electronic transmission of ICSRs and use their locally established ICH compliant data-processing network (Gateway) and management system, may wish to attend this course to learn how to access and query the ICSRs that they have submitted to EudraVigilance.

- National Competent Authorities that wish to acquire knowledge about the functionalities of the tool, specifically in relation to data retrieval and evaluation to facilitate the scientific use of the data contained in the database.

Course Goals

The primary goals of this course are to allow participants to:

- Acquire a robust knowledge in the fundamentals of the electronic reporting of ICSRs
- Familiarise themselves with the electronic transmission of ICSRs and the ICH M2 safety and acknowledgment message specifications
- Understand and apply the ICH E2B(R2) specifications on clinical safety data management in the frame of good pharmacovigilance practices as well as the current EudraVigilance Business Rules
- Get hands on experience with the EudraVigilance reporting capabilities and query functions

Course Audience

The course is intended for people in charge of pharmacovigilance and drug safety in MAHs and National Competent Authorities with legal reporting obligations in the EEA. The target audience of this training course also includes, but is not limited to:

- Qualified persons for pharmacovigilance
- Pharmacovigilance experts
- Data entry professionals
- Medical coding professionals
- Persons interested in building or updating their knowledge in electronic adverse reaction reporting

Details of the Course

Duration: 3 days
Location: European Medicines Agency (EMA)
Canary Wharf
7 Westferry Circus
London, E14 4 HB, UK

The course is limited to 16 participants. Register early.

The content of this training course is subject to regular updates in order to comply with new regulations and requirements.
### DAY ONE

**Module I: Fundamentals of Electronic Reporting of ICSRs**

**09:00** Introduction
- **Session 1**
  - Concepts of Electronic Transmission of ICSRs
  - Introduction to EudraVigilance
  - Registration with EudraVigilance
- **Session 2**
  - Clinical Safety Data Management and Transmission of ICSRs - ICH E2B(R2)

**10:30** COFFEE BREAK
- **Session 3**
  - EudraVigilance Gateway and WEB Trader
- **Session 4**
  - ICSR Validation Business Rules

**12:30** LUNCH
**13:00** Session 5
- Creating a Safety Message

**15:30** COFFEE BREAK
- **Session 6**
  - Follow-up Report
- **Session 7**
  - Nullification Report
- **Session 8**
  - Literature Report

**18:00** END OF DAY 1

### DAY TWO

**Module II: Creating and Validating ICSRs (cont'd)**

**09:00** Session 9
- Parent-child Report

**09:45** Session 10
- Report with Medical and Drug History

**10:30** COFFEE BREAK
- **Session 11**
  - Study Report
  - EudraVigilance Business Rules

**12:30** LUNCH
**13:30** Session 13
- Receiving Acknowledgment Messages

**15:30** COFFEE BREAK
- **Session 14**
  - Validating and Creating Acknowledgments

**17:45** END OF DAY 2

### DAY THREE

**Module III: Query Functions, MedDRA in EudraVigilance**

**09:00** Session 17
- MedDRA Simple and Advanced Queries

**10:30** COFFEE BREAK
- **Session 18**
  - ICSR Simple and Advanced Queries

**12:00** SANDWICH LUNCH

### Module IV: Competency Assessment

**15:00** Questions

**16:00** END OF DAY 3

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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.
Learning Objectives

By the end of this training course, you should be able to do the following within the context of EudraVigilance:

- Apply ICH rules to safety reporting
- Describe the Registration process with EudraVigilance
- Understand the Concepts of Electronic Transmission of ICSRs
- Describe the EudraVigilance Gateway
- Describe the WEB Trader functions
- Explain the reporting processes for fully-automated organisations, Post-function users, and EVWEB users
- Create, validate and send safety messages
- Create, validate and send:
  - Follow-up reports
  - Nullification reports
  - Literature reports
  - Parent-child reports
  - Study reports
  - Reports with medical and drug history
- Apply EudraVigilance business rules
- Create and send acknowledgments of received ICSR messages
- Query, view, browse and download safety reports
- Query, view and browse MedDRA through the EVWEB

What this Training Course Is

It is important that you have the proper expectations of what will be covered in this course. This course is:

- Training on the EudraVigilance system, specifically the EVWEB
  - How the system relates to the ICH E2B(M) guideline
  - How to navigate the system
  - How to enter information
  - Mandatory fields
- Training on the WEB Trader for transmission of documents on the EudraVigilance Gateway
- Instruction on using EVWEB to browse MedDRA

What this Training Course Is Not

It is important that you have the proper expectations of what will not be covered in this course. This course is not:

- Training on pharmacovigilance practices
- Consulting on your company’s business rules
- MedDRA training
- Training on data entry in the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)

DIA Upcoming Training Courses in Safety and Pharmacovigilance

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

Benefit/Risk Management
24-25 May 2011 | Munich, Germany | ID 12561

EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing
13-17 February 2012 | London, United Kingdom | ID 12551
1-5 October 2012 | Vienna, Austria | ID 12566

How to Prepare for Pharmacovigilance Audits and Inspections
9-10 May 2012 | Basel, Switzerland | ID 12556
November 2012 | Location to be confirmed | ID 12575

Introduction to Signal Detection and Data Mining in Pharmacovigilance
8-9 May 2012 | Basel, Switzerland | 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

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

IDMP Information Day at the European Medicines Agency
21 February 2012 | London, United Kingdom | ID 12581
8 May 2012 | London, United Kingdom | ID 12537
4 December 2012 | London, United Kingdom | ID 12536

ICSR Information Day at the European Medicines Agency
4 May 2012 | 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 2011 | London, United Kingdom | ID 12540

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

Course Pre-requisites

Participants are expected to have a minimal background knowledge of:

- EU Community legislation and guidance documents related to the monitoring of safety of clinical trials and post-authorisation pharmacovigilance activities
- Working with a PC

For newcomers in Pharmacovigilance, a special 1 day course “Introduction to PharmacoVigilance” has been developed. Please consult the DIA website for more information.

Hotel Information

Attendees have to make their own reservation.

Recommended hotel close to the EMA: 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

DIA was able to negotiate a special rate for participants to the EudraVigilance training course.

Room rate is GBP 139.00 (2011 rate) per room incl. breakfast excl. VAT

To book a room, click here. Please fill in corporate account number: 481223696.

The hotel is situated opposite of Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance to the EMA (2 min).

I wish to attend the following course in 2012:

1st choice

- 16-18 January 2012 ID#12501
- 6-8 February 2012 ID#12505
- 5-7 March 2012 ID#12509
- 18-20 April 2012 ID#12513
- 21-23 May 2012 ID#12515

2nd choice

- 10-12 September 2012 ID#12517
- 17-19 September 2012 ID#12519
- 17-19 October 2012 ID#12521
- 22-24 October 2012 ID#12523
- 12-14 November 2012 ID#12525

Standard fee €1'550.00
Reduced Fee for Academy and Full Government €775.00

TOTAL AMOUNT DUE: €

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

CONTACT INFORMATION

Contract Service Organisation
European Medicines Agency, London, UK
EudraVigilance - Electronic Reporting of ICSRs in the EEA

REGISTRATION FORM
EudraVigilance - Electronic Reporting of ICSRs in the EEA
European Medicines Agency, London, UK

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52
or email to: Roxann.Schumacher@diaeurope.org

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.

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)

Please indicate your professional category:

Academia Government Industry Contract Service Organisation

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
Expiration 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 # 15582 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. 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.

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