EudraVigilance

Electronic Reporting of ICSRs in the EEA

DRUG INFORMATION ASSOCIATION

A JOINT INITIATIVE OF THE EMEA WITH DIA ACTING AS THE CONFERENCE ORGANISER
AT THE REGUS BANK CENTER BUDAPEST, SZABADSÁG TÉR 7, 1054 BUDAPEST, HUNGARY FROM JULY 5-7, 2006

Introduction

EudraVigilance is the European data-processing network and management system, established at the European Medicines Agency (EMEA) 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 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 Europe.

Community legislation is in place to ensure that all stakeholders, including National Competent Authorities and pharmaceutical companies in the EEA collect, collate and exchange adverse drug reactions.

The implementation of 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), is currently a top priority in the area of pharmacovigilance at Community level to make data exchange and management more efficient.

EVWEB, the Internet-based reporting tool developed at the EMEA, was released in 2004 to allow Small and Medium Size Enterprises (SMEs) that hold marketing authorisations in the EEA, to report electronically adverse reactions, in full compliance with the internationally agreed standards, to the EMEA and National Competent Authorities. Further, EVWEB helps regulators in the Community to manage the constantly increasing volume of adverse reaction reports more efficiently. In addition, EVWEB was extended to integrate the new reporting requirements of suspected serious unexpected adverse reactions (SUSARs) as a result of the EU Directive on Clinical Trials.

The EudraVigilance Training Programme has been designed for:

- SMEs that intend to use EVWEB to implement electronic transmission of safety data. SMEs will be required to follow a training course in order to ensure the correct use of the reporting tool. SMEs can apply for more than one person to be trained, or alternatively, send only one person who will subsequently train other users internally.
- Pharmaceutical companies that perform electronic transmission of ICSRs and wish to access the information related to their own ICSRs and medicinal products contained in the system. Using this locally established ICH compliant data-processing network (Gateway) and management system, pharmaceutical companies 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 in 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 Overview

This course will be the only training programme officially recognised by the EMEA. The EMEA will present successful candidates with a 'Certificate of Completion' based on a competency assessment at the end of the course. Certified candidates will be eligible to train other potential users within their organisation.

The EudraVigilance training programme is open to Contract Research Organisations (CROs), Consultants and other organisations with an interest in the EudraVigilance project. However, it should be noted that the persons attending the training will only be given access the EudraVigilance training environment for a period of two months. After this period the EudraVigilance system will only be available for these organisations if they act on behalf of a Marketing Authorisation Holder (MAH) or a Sponsor of a Clinical Trial and that this is notified to the EMEA in writing and through the EudraVigilance registration process.

Details of the Course

Duration: 3 days
Location: Regus Bank Center Budapest, Hungary
Capacity: Each course is limited to 20 participants

Course Goals

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

- Acquire a robust base 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(M) specifications on clinical safety data management in the frame of good pharmacovigilance practices
- Get hands on experience with the EudraVigilance reporting capabilities and query functions
- Understand the concepts of the EudraVigilance Medicinal Product Dictionary and get some practical experience in working with it

Course Audience

The training 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
- Dictionary and data management specialists and personnel
- Persons interested in building or updating their knowledge in electronic adverse reaction reporting

Course Pre-requisites

Participants in this training course should preferably be registered with EudraVigilance before training (for details visit http://eudravigilance.emea.eu.int).
Participants in this training programme will be expected to have a sound and detailed knowledge of:

- EU Community legislation
- EU guidelines and procedures related to pharmacovigilance
- ICH E2B(M) and M2 guidelines and standards
- MedDRA terminology
- Working with a computer

Course Agenda

Electronic Reporting of ICSRs in the EEA

EudraVigilance

Day One

Module I: Fundamentals of Electronic Reporting of ICSRs

09:00 **Introduction**

09:30 **Session 1**
Concepts of Electronic Transmission of ICSRs

10:10 **Session 2**
Clinical Safety Data Management and Transmission of ICSRs - ICH E2B(M)

10:40 **Questions**

11:00 Coffee break (included in the registration fee)

11:10 **Session 3**
EudraVigilance Gateway and WEB Trader

11:30 **Session 4**
ICSR Validation Business Rules (Session will be continued after lunch)

12:20 **Questions**

12:30 Lunch (included in the registration fee)

Module I: Fundamentals of Electronic Reporting of ICSRs (cont'd)

13:30 **Session 4:**
ICSR Validation Business Rules (continued)

Module II: Creating and Validating ICSRs

14:30 **Session 5**
Creating a Safety Message

15:30 Coffee break (included in the registration fee)

15:45 **Session 6**
Follow-up Report

16:15 **Session 7**
Nullification Report

16:45 **Session 8**
Literature Report

17:30 **Questions**

17:45 End of day 1

Day Two

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

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

09:15 **Hands-on Activity: Parent-child Report**

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

10:00 **Session 11**
Study Report

10:30 **Session 12**
Saving and Printing Options

11:00 Coffee break (included in the registration fee)

11:55 **Session 13**
Validation and Creating Acknowledgments

12:25 **Session 14**
Receiving Acknowledgment Messages

12:40 **Session 15**
WEB Trader - Post Function

Session 16
What To Do in the Event of System Failure

13:00 Lunch (included in the registration fee)

Module III: EudraVigilance Medicinal Product Dictionary

14:00 **Session 17**
EudraVigilance Medicinal Product Dictionary (EVMPD)

15:30 Coffee break (included in the registration fee)

15:45 **Session 18**
Creating EudraVigilance Product Report Messages: Product Report With Operation Type Insert

16:30 **Session 19**
Creating EudraVigilance Product Report Messages With Different Operation Types

17:30 **Questions**

17:45 End of day 2

Agenda continued on next page

EudraVigilance User Training

Day Three

Module IV: Query Functions, MedDRA in EudraVigilance

09:00 **Session 20**
EVMPD Simple and Advanced Queries

09:30 **Session 21**
MedDRA Simple and Advanced Queries

10:00 **Session 22**
ICSR Simple and Advanced Queries

10:30 **Questions and review for competency assessment**

12:00 Lunch (included in the registration fee)

Module V: Competency Assessment

13:00 **Competency Assessment**

- Part 1: Online Assessment Questions
- Part 2: ICSR Exam Case
- Part 3: Product Report Exam Case

15:00 End of day 3

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 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
- Create and send acknowledgments of received ICSR messages
- Query, view, browse and download safety reports
- Create, send and follow up on medicinal product reports
- Query, view, browse and download medicinal products in the EudraVigilance Medicinal Product Dictionary
- 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 the EudraVigilance Medicinal Products Dictionary
- 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 Course Cancellation Policy

BEFORE 28 OF JUNE, 2006

An administrative fee will be deducted from the registration fee: EUR 200.00

Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. Cancellations must be in writing. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. If the event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Registration Form - ID #06542

Fax to: +352 26 33 00 72

EudraVigilance

DIA Drug Information Association

EudraVigilance - Electronic Reporting of ICSRs in the EEA

emea

A Joint initiative of the EMEA

with DIA acting as the conference organiser

at the Regus Bank Center Budapest, Szabadság tér 7, 1054 Budapest, Hungary

July 5 - 7, 2006

Registration will be accepted by fax or email - Registration includes training course material. Refreshments and lunch are included.
This course will be limited to 20 participants - The course may be cancelled due to low enrollment

Standard Fee: EUR 1,580.00 **VAT: EUR 284.40** **Total Amount: EUR 1864.40** ❑

Registrant

❑ Prof. ❑ Dr. ❑ Ms. ❑ Mr.

Last Name Company

First Name & Middle Initial Job Title

Street Address / P.O. Box

Postal Code City Country

(*)Telephone (*)Telefax

Email

VAT No

Payment

❑ **Bank transfers should be made in EURO to following bank:**

Banque du Luxembourg, 14 Boulevard Royal, Luxembourg - Account holder: DDCS S.A.
IBAN: LU56 0081 1291 2000 2003 - BIC: BLUX LULL

Account Holders Name and Contact Details: DDCS S.A., 55-57 Rue de Merl, 2146 Luxembourg, Luxembourg

Your name and company must be included on the transfer document to ensure payment allocation.

Please fax this form to + 352 26 33 00 72 or email to ddcs@ddcs.lu.

The course fee has to be paid in full prior to the training course, otherwise registration cannot be guaranteed.

Please include 'EudraVigilance registration 06542' in the email subject field.

Confirmation of registration will be sent if requested.
Otherwise confirmation of participation will be sent when the payment is received.

European Branch Office
Elisabethenanlage 11, Postfach
4002 Basel, Switzerland
Phone: +41 61 225 51 51
Fax: +41 61 225 51 52
E-Mail: diaeurope@diaeurope.org

Worldwide Headquarters
800 Enterprise Road, Suite 200
Horsham, PA 19044-3595
Phone: +1 215 442 6100
Fax: +1 215 442 6199
E-Mail: dia@diahome.org

Drug Information Association LLC (Japan)
Level 2, Toranomon 10 Mori Building
1-18-1, Toranomon, Minato-ku, Tokyo 105-0001, Japan
Phone: +81 3 5511 1131
Fax: +81 3 5511 0100
E-Mail: diajapan@diajapan.org