EudraVigilance

Electronic Reporting of ICSRs in the EEA

DRUG INFORMATION ASSOCIATION

A Joint initiative of the EMEA with DIA acting as the conference organisers
at Regus Bratislava, Nam. 1. maja 11, 811 06 Bratislava, Slovakia

Introduction

EudraVigilance is the European data-processing network and management system, established at the European Agency for the Evaluation of Medicinal Products (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, will be 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 the 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

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 Bratislava, Nam. 1. maja 11, 811 06 Bratislava, Slovakia
Capacity: The course is limited to15 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 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 Break

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

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 Break

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

10:00 **Hands-on Activity: Parent-child Report**

11:00 Break

11:15 **Session 10**
Report with Medical and Drug History

11:30 **Session 11**
Study Report

11:45 **Session 12**
Saving and Printing Options

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

Module III: EudraVigilance Medicinal Product Dictionary

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

15:30 Break

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 Break

Module V: Competency Assessment

13:00 **Competency Assessment**

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

16:30 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

PRIOR TO 5 DAYS BEFORE THE COURSE:

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. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Registration Form - ID #07527

Fax to: +41 61 225 51 52

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 organisers

At Regus Bratislava, Nam. 1. maja 11, 811 06 Bratislava, Slovakia

Date 12-14 February, 2007

Registration will be accepted by mail, fax or email - Registration includes training course material and coffee-breaks; lunch is not included
This course will be limited to 15 participants - The course may be cancelled due to low enrollment

Standard Fee: EUR 1,550.00	**VAT 19%: EUR 294.50**	**Total Amount: EUR 1844.50**	❑
Reduced Fee: EUR 775.00	**VAT 19%: EUR 147.25**	**Total Amount: EUR 922.25**	❑

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:** **Payment by credit card cannot be accepted**

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, company and course I.D. code must be included on the transfer document to ensure payment allocation.

Please fax this form to + 41 225 51 52 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 Slovakia' 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.

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