EudraVigilance

Electronic Reporting of ICSRs in the EEA

A joint initiative of the EMEA and AEMPS with DIA and ESAME FOUNDATION acting as the conference organisers at Agencia Española de Medicamentos y Productos Sanitarios , Majadahonda, Madrid, Spain

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.

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: Agencia Española de Medicamentos y Productos Sanitarios, Majadahonda, Madrid, Spain
Capacity: Each course is limited to 15 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

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 (available in-house, 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 Coffee 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 Coffee 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 (available in-house, included)

Module III: EudraVigilance Medicinal Product Dictionary

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

15:30 Coffee 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

Recommended hotels nearby

Hotel Majadahonda****

www.hotelmajadahonda.com

Attendees must make their own reservation

EudraVigilance User Training

Day Three

A mid-morning coffee break will be provided.

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 (available in-house, included)

A mid-afternoon coffee break will be provided

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

BEFORE 18 JANUARY

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 ESAME FOUNDATION of any such substitutions as soon as possible. If the event is cancelled, DIA or ESAME FOUNDATION are not responsible for airfare, hotel or other costs incurred by registrants.

Registration Form - ID #06530

Fax to: +34 93 213 69 48

EudraVigilance - Electronic Reporting of ICSRs in the EEA

A joint initiative of the EMEA and AEMPS with DIA and ESAME FOUNDATION as the conference organisers

at Agencia Española de Medicamentos y Productos Sanitarios,

Ctra. de Majadahonda-Pozuelo, km 2, 28220 Majadahonda, Madrid, Spain

January 24- 26, 2006

Registration will be accepted by mail, fax or email - Registration includes training course material, coffee-breaks and lunch.
This course will be limited to 15 participants - The course may be cancelled due to low enrollment

Standard Fee: EUR 1,550.00 **VAT 16%: EUR 248.00** **Total Amount: EUR 1798.00**

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 _____

E-Mail _____

❑ En cumplimiento del artículo 5 de la Ley Orgánica 15/1999, de 13 de diciembre de Protección de Datos de Carácter Personal, se le informa que sus datos de carácter personal se incluyen en un fichero cuya finalidad es gestionar el curso y enviar las claves de acceso necesarias para el mismo asi como enviar información de las actividades relacionadas con DIA y la Fundación ESAME. Dichos datos serán cedidos a DIA en Suiza para dicha finalidad. Podrá ejercitar los derechos de acceso, rectificación, cancelación y oposición ante la Fundación ESAME, como responsable del fichero y tratamiento, enviando un e-mail a: esame@esame.org.

❑ Following Spanish Perstonal Data Protection Law 15/1999 of 13th December 1999, you are informed that the personal data will be included in a data base which objective is to manage the course and send the registrants the required access code to the course, as well as to inform of any activity related to DIA and ESAME Foundation. These data will be transfered to DIA in Switzerland. You may exert your right to access, modify, cancel or oppose your information to the responsible of the database and its treatment by sending an e-mail to esame@esame.org.

Signature _____ (Please sign name in full)

Payment

❑ **Cheque payable to FUNDACION PRIVADA ESAME**

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

Banco Sabadell - FUNDACION PRIVADA ESAME - Account Number: IBAN ES05 0081 0059 2100 0120 6922 BIC: BSABESBB

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

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