EudraVigilance Training

Electronic Reporting of ICSRs in the EEA

A joint initiative of the European Medicines Agency
with DIA acting as the conference organiser

Course #12151
12-14 December 2012
Infarmed, I.P., Lisbon, Portugal

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: INFARMED, I.P.
Parque de Saúde de Lisboa
Av. Brasil, 53
1749-004 Lisboa - Portugal

The course is limited to 16 participants. Register early.

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 Overview

This course is the only training programme officially recognised by the European Medicines Agency.
Participants that pass the knowledge evaluation following the course will receive a certificate that will allow them to register with EudraVigilance and to report ICSRs to the European Medicines Agency and/or the National Competent Authorities in the EEA.
The EudraVigilance training programme is open to Contract Research Organisations (CROs), consultants and other organisations with an interest in the EudraVigilance project. It should be noted that the persons attending the training will only be given access to the EudraVigilance training environment for a period of two months.
After this period the EudraVigilance system will only be available to those organisations that act on behalf of a MAH, a Sponsor of a Clinical Trial or an NCA and that this is notified to the European Medicines through the EudraVigilance registration process.

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

EudraVigilance

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA®
www.diahome.org

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

Module II: Creating and Validating ICSRs

13:30 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

Session 12
Saving and Printing Options

12:30 LUNCH

13:30 Session 13
Receiving Acknowledgment Messages

Session 14
Validation and Creating Acknowledgments

15:30 COFFEE BREAK

Session 15
WEB Trader - Post Function

Session 16
What To Do in the Event of System Failure

17:45 END OF DAY 2

DAY THREE

Module III: Query Functions, MedDRA in EudraVigilance

09:00 Session 17
MedDRA Simple and Advanced Queries

Session 18
ICSR Simple and Advanced Queries

10:30 COFFEE BREAK

Questions and review for knowledge evaluation

12:00 SANDWICH LUNCH

Module IV: Knowledge evaluation

Knowledge evaluation

- Part 1: Multiple Choice Questions
- Part 2: ICSR Exam Case

15:00 Questions

16:00 END OF DAY 3

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 (X-EVMPD)

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
  http://eudravigilance.emea.europa.eu/human/euPoliciesAndDocs.asp
- 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 must make their own bookings.
Recommended hotels nearby:

VILLA RICA HOTEL
Avenida 5 de Outubro, 295
1600-035 Lisboa
Phone: +351 210 043 000
Fax: +351 210 043 998
http://www.villaricahotelsgroup.com/VillaRica/en/Hotel/VillaRicaLisboa.aspx

RADISSON SAS HOTEL
Av Marechal Craveiro Lopes 390,
1749-009 Lisbon
Phone: 351 (21) 004-5000
Fax: 351 (21) 004-5001
http://www.radissonblu.com/hotel-lisbon

REGISTRATION FORM

Electronic Reporting of ICSRs in the EEA

Course #12151 | 12-14 December 2012 | Infarmed, I.P., Lisbon, Portugal

ID #12151

DIA www.diahome.org

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52
or email to: Gabriella.Sokoli@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. * All fees are subject to local 23% VAT

Standard fee*	€ 1'550.00 ❑
Reduced Fee* for Academia and Full Government	€ 775.00 ❑

SPECIAL DISCOUNT FOR SME (STATUS CONFIRMED BY EMA) AVAILABLE. PLEASE CONTACT THE DIA.
NOTE: PAYMENT OF REGISTRATION FEES MUST BE RECEIVED BEFORE COMMENCEMENT OF THE COURSE

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

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

Email (Required for confirmation)

For company billing, please add your company's VAT number: _____

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

Expiry 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, Kuechengasse 16, 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# 12151 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
Regretfully, 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.

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.

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

© DIA 2012