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 #14515
20-22 October 2014
Grand Hotel San Marino, Republica di San Marino (RSM)

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: GRAND HOTEL SAN MARINO
Viale Antonio Onofri, 31
47890 Repubblica di SanMarino
RSM

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

Participants who pass the knowledge evaluation following the course will receive a notification from the European Medicines Agency 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 with 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

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 book their room directly at the Grand Hotel San Marino.

The hotel offers a special rate for participants of the EudraVigilance training course:

EUR 82.00 for single occupancy
EUR 102.50 for double occupancy

These rates are per room and night and include buffet breakfast

For hotel bookings please call the hotel or use the booking form on the DIA website.

Travel Information

By Air

"F.Fellini" Airport Rimini-San Marino 27 km www.riminiairport.com
"L.Ridolfi" Airport Forlì 72 km www.forliairport.com
"G. Marconi" Airport Bologna 132 km www.riminiairport.com

By Train

The closest train station is RIMINI RAILWAY STATION
For buses from Rimini to San Marino, please check :
http://www.ferroviedellostato.it/homepage_en.html
For more information about San Marino, please consult the following website:
http://www.visitsanmarino.com/default.asp?id=81

DIA Upcoming Training Courses in Safety and Pharmacovigilance

- **Benefit/Risk Management**
  19-20 May 2014 | Prague, Czech Republic | ID 14533
  10-11 November 2014 | Barcelona, Spain I ID 14547
- **Signal Management in Pharmacovigilance**
  21-22 May 2014 | Prague, Czech Republic | ID 14534
  November 2014 | Paris, France I ID 14549
- **Pre-Marketing Clinical Safety**
  16-17 June 2014 | Amsterdam, The Netherlands | ID 14539
- **Post-Authorisation Safety Studies (PASS)** **NEW OFFERING!**
  18-19 June 2014 | Amsterdam, The Netherlands | ID 14535
- **Medical Approach in Diagnosis and Management of ADRs**
  22-23 September 2014 | Paris, France I ID 14540
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  23-24 September 2014 | Paris, France I ID 14544
- **ICH Endorsed Pharmacovigilance**
  21 October 2014 | Dakar, Senegal I ID 14559
  November 2014 | Algiers, Algeria I ID 14560
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  November 2014 | Paris, France I ID 14550

European Medicines Agency Information Days and Courses

- **ICSR Information Day**
  13 May 2014 | London, United Kingdom | ID 14502
- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  13-17 October 2014 | London, United Kingdom I ID 14548
- **EudraVigilance courses:**
  EudraVigilance – Electronic reporting of ICSR
  eXtended EudraVigilance Medicinal Product Dictionary
  Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For information on EudraVigilance courses, please visit www.diahome.org > Meetings & Training > About Meetings & Training > In-Person Instruction > EudraVigilance > EudraVigilance Courses

REGISTRATION FORM

EudraVigilance - Electronic Reporting of ICSRs in the EEA
Course #14515 | 20-22 October 2014 | Grand Hotel San Marino, Republica di San Marino (RSM)

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

FEES

Standard Fee	€	1'745.00	❑
Reduced Fee Academia/Non Profit/Government (Full Time)	€	865.00	❑

Special discount - for SME (status confirmed by EMA) available.

The registration fee includes training course material, IT equipment, lunches and refreshments.

TOTAL AMOUNT DUE: _____

Each course is limited to 16 participants.
Courses may be cancelled if numbers of participants are not sufficient.

Payment of registration fees must be received before commencement of the course.

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Event ID 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 100.00.

If you do not cancel five working days prior to the event 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. Please notify the DIA Europe office of any such substitutions as soon as possible.