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 #13156
2-4 October 2013
Novotel Bucharest City Centre Hotel, Bucharest, Romania

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: Novotel Bucharest City Centre Hotel
Calea Victoriei 37B Sector 1
010061 Bucharest
Romania

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

Session 6
Saving and Printing Options

15:30 COFFEE BREAK

Session 7
Follow-up Report

Session 8
Nullification Report

18:00 END OF DAY 1

DAY TWO

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

09:00 Session 9
Literature Report

Session 10
Parent-child Report

Session 11
Report with Medical and Drug History

10:30 COFFEE BREAK

Session 12
Study Report
EudraVigilance Business Rules

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

Please contact Ms. Madalina Nedelciu from Business Travel to book a hotel room, flight or airport transfer. She will be pleased to assist you.

S.C. BUSINESS TRAVEL TURISM S.R.L.
Aleea Alexandru nr. 9A, 1st Distict,
011821 Bucharest
Romania

Tel. +4 021 2315619
Fax. +4 021 2315622
Email: madalina.nedelciu@businesstravel.ro

DIA Upcoming Training Courses in Safety and Pharmacovigilance

■ **Benefit/Risk Management**
26-27 September 2013 | Prague, Czech Republic | ID 13524

■ **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
19-20 September 2013 | Paris, France | ID 13563

■ **How to Prepare for Pharmacovigilance Audits and Inspections**
11-12 June 2013 | Amsterdam, Netherlands
7–8 November 2013 | Paris, France

■ **ICH Endorsed Pharmacovigilance**
22-23 September 2013 | Muscat, Sultanate of Oman | ID 13568

■ **Pre-Marketing Clinical Safety**
Next recurrence of this course to be announced

■ **Signal Management in Pharmacovigilance**
6–7 November 2013 | Paris, France

European Medicines Agency Information Days and Courses

■ **EudraVigilance Information Day**
22 October 2013 | London, United Kingdom | ID 13530

■ **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
18-22 November 2013 | London, United Kingdom | ID 13522

■ **IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day**
10 November 2013 | London, United Kingdom | ID 13531

■ **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 course details on EV, please click here.For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses.

REGISTRATION FORM

EudraVigilance - Electronic Reporting of ICSRs in the EEA

Course #13156 | 2-4 October 2013 | Novotel Bucharest City Centre Hotel, Bucharest, Romania

FEES

Standard Fee*	€	1'745.00 ❑
Reduced Fee for Academia/Government/ Non-profit (Full-Time)*	€	865.00 ❑

*Rates are subject to Romanian VAT at 24%.

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

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

TOTAL AMOUNT DUE: _____

This course is limited to 16 participants.
This course 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

After reception of your payment, Business Travel will send you a confirmation/invoice.

❑ **Bank transfers:**

Participants from Romania will be charged in RON.

S.C. BUSINESS TRAVEL TURISM S.R.L.

Aleea Alexandru nr. 9A, 1st Distict,

011821 Bucharest

Romania

Tel. +4 021 2315619

Fax. +4 021 2315622

Bank Address: RBS BANK Bucharest Romania

Swift code - ABNAROBU

IBAN: RO91ABNA4100264100071850

Payment should include your name, company and the remark „EudraVigilance" to ensure correct allocation of your payment.

❑ **Credit Card**
If you wish to pay by credit card, please contact Business Travel.

Date	Signature

Cancellation Policy

Cancellations must be made in writing and be received at the Business Travel office seven working days prior to the course start

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Standard EUR 200.00 - Reduced EUR 100.00
Registered attendees who do not cancel seven working days prior to the course start date and do not attend, will be responsible for the full registration fee.
Business Travel reserves the right to alter the venue and dates if necessary. If an event is cancelled Business Travel is not responsible for airfare, hotel or other costs incurred by registrants. Registered attendees are responsible for cancelling their own hotel and travel reservations.Transfer Policy

Tansfer Policy

You may transfer your registration to a colleague prior to the start of the event. Please notify the Business Travel 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 Business Travel. If you have not received your confirmation within seven working days, please contact Business Travel.