

# EudraVigilance Training

## Electronic Reporting of ICSRs in the EEA

Course #10576

25-27 August 2010

INFODOM, Andrije Zaje 61/I, 10 000 Zagreb, Croatia



### 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 (EVMPD) and get some practical experience in working with it

### 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
- Dictionary and data management specialists and personnel
- Persons interested in building or updating their knowledge in electronic adverse reaction reporting

**The course is limited to 16 participants. Register early.**

### A European Medicines Agency initiative with the support of HALMED (Agency for Medicinal Products and Medical Devices) Croatia

#### 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 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 (NCAs) 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 European Medicines Agency, 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 European Medicines Agency and NCAs. 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 Unexpected Serious 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 is the only training programme officially recognised by the European Medicines Agency. The successful candidates will be provided with a 'EudraVigilance User Training Course Certificate' based on a competency assessment at the end of the course. Certified candidates will be eligible to train other users within their organisation.

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 European Medicines Agency in writing and through the EudraVigilance registration process.



## COURSE AGENDA

## 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 (included in the registration fee)

## 11:10 Session 3

EudraVigilance Gateway and WEB Trader

## 11:30 Session 4

ICSR Validation Business Rules

## 12:20 Questions

## 12:30 Lunch (included in the registration fee)

## Module II: Creating and Validating ICSRs

## 13:30 Session 5

Creating a Safety Message

## 15:30 Coffee break (included in the registration fee)

## 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

## 09:15 Hands-on Activity: Parent-child Report

## 09:45 Session 10

Report with Medical and Drug History

## 10:00 Session 11

Study Report

## 10:30 Session 12

Saving and Printing Options

## 11:00 Coffee break (included in the registration fee)

## 11:15 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 in the registration fee)

## Module III: EudraVigilance Medicinal Product Dictionary

## 14:00 Session 17

EudraVigilance Medicinal Product Dictionary (EVMPD)

## 15:30 Coffee break (included in the registration fee)

## 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

## 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

## 10:15 Coffee break (included in the registration fee)

## 10:30 Questions and review for competency assessment

## 12:00 Lunch (included in the registration fee)

## Module V: Competency Assessment

## 13:00 Competency Assessment

- Part 1: Multiple Choice Questions
- Part 2: ICSR Exam Case
- Part 3: Product Report 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 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

## Course Information

The course will take place at the:

**INFODOM**

Andrije Zaje 61/1  
10 000 Zagreb  
Croatia

## Hotel Information

**Attendees must make their own reservation.**

Recommended hotel nearby :

Four Points by Sheraton  
Panorama Zagreb  
Trg Kresimira Cosica 9  
10 000 Zagreb, Croatia  
Tel. +385 1 3658333  
<http://www.hotel-fourpointspanorama.com/>

## DIA Upcoming Training Courses on Safety and Pharmacovigilance

**Excellence in Pharmacovigilance: Clinical Trials and Post Marketing**

25-29 October 2010 | Vienna, Austria | ID 10533

**Introduction to Signal Detection and Data Mining in Pharmacovigilance**

7 October 2010 | London, United Kingdom | ID 10558

**How to Prepare for Pharmacovigilance Audits and Inspections**

8 October 2010 | London, United Kingdom | ID 10559

**Medical Approach in Diagnosis and Management of ADRs**

13-14 September 2010 | Paris, France | ID 10531

**Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing**

1-3 December 2010 | Paris, France | ID 10526

**EudraVigilance Information Day at the European Medicines Agency**

19 October 2010 | London, United Kingdom | ID 10535

**EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)**

Courses throughout the year | European Medicines Agency, London, UK and selected European cities

For course details on EV, please visit [www.diahome.org](http://www.diahome.org) > Training > EudraVigilance > Click on Related Courses

# REGISTRATION FORM

ID# 10576

EudraVigilance - Electronic Reporting of ICSRs in the EEA  
25-27 August 2010 – INFODOM, Andrije Zaje 61/I, 10 000 Zagreb, Croatia

**FAX YOUR COMPLETED REGISTRATION FORM TO: +385 1 4884 110**  
**OR EMAIL TO: NUSPOJAVE@HALMED.HR**

Each course is limited to 16 participants. The registration fee includes training course material, IT equipment, lunches and refreshments. The course may be cancelled if numbers of participants are not sufficient.

**Standard Fee** HRK 3.500,00 + VAT 23%: HRK 805,00 **Total Amount: HRK 4.305,00**

**Note: Payment of registration fees must be received before commencement of the course**

## REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'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 (Required for confirmation)	Email (Required to receive presentation download instructions)

**Please indicate your professional category:**  Academia  Government  Industry  Contract Service Organisation

## PAYMENT METHODS

**Only Bank transfer: The Agency will give further instructions after receiving your registration via e-mail or fax.**

**Bank transfers:** Bank transfers: When HALMED 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 HRK should be addressed to "Account Holder: HALMED." including your name, company, Meeting ID#10576 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.**

**Please indicate your identification number – "OIB" :**

**Note : Without this number, we will not be able to generate your invoice**

## CANCELLATION POLICY

Cancellations must be made in writing and be received at the HALMED office five working days prior to the course start

**Cancellations are subject to an administrative fee:**

Full Meeting Cancellation: Industry (Member/Non-member) = HRK 1440.00 - Government/Academia/Non-profit (Member/Non-member) = HRK 720.00

Registrants who do not cancel five working days prior to the course start date and do not attend, will be responsible for the full registration fee. HALMED reserves the right to alter the venue and dates if necessary. If an event is cancelled HALMED is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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 HALMED 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 HALMED. If you have not received your confirmation within five working days, please contact HALMED.**