

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 #11588 | 5-7 September 2011
INFODOM, 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(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: INFODOM

Andrije Zaje 61/1

10 000 Zagreb, Croatia

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

New Format of this three day course with more time for hands-on activities!

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 competency assessment 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.

Note: The course will NOT address aspects related to the data entry of medicinal product information in the EudraVigilance Medicinal Product Dictionary (EVMPD).

Personnel of organisations responsible for entering medicinal product data in the EVMPD need to attend the EVMPD training course.



COURSE AGENDA

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 (not included)

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 (not included)

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 competency assessment

12:00

Lunch (not included)

Module IV: Competency Assessment

Competency Assessment

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

15:00

Questions

16:00

End of day 3

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.

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 of the EudraVigilance Medicinal Product Dictionary (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.

Course Information

The course will take place at:

INFODOM
Andrije Zaje 61/1
10 000 Zagreb, Croatia

Hotel Information

Obzor was able to block some rooms at a preferable rate of EUR 90,- per room per day, breakfast and VAT included in the Four Points by Sheraton Panorama Hotel. The City tax is EUR 1,- per person per day is excluded. Please contact Obzor to book a room.

Flight Information

Obzor will be happy to organise your flight for you. Please contact Obzor for more information

OBZOR PUTOVANJA d.o.o.
Teslina 5
10000 ZAGREB
TEL. +385 1 6160 242
FAX +385 1 6160 240

REGISTRATION FORM

EudraVigilance - Electronic Reporting of ICSRs in the EEA
5-7 September 2011 | INFODOM, Zagreb, Croatia

ID# 11588

FAX YOUR COMPLETED REGISTRATION FORM TO

OBZOR PUTOVANJA d.o.o., Teslina 5, 10000 Zagreb, Croatia: +385 1 6160 240

OR EMAIL TO: obzor@croatiaairlines.hr

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

Standard Fee	EUR 1'550.00 plus 23%VAT EUR 356.50 HRK 11'625,00 plus 23% VAT HRK 2'673,75	TOTAL EUR 1'906.50 for participant from the EEA <input type="checkbox"/> TOTAL HRK 14'298.75 for participants from Croatia <input type="checkbox"/>
Reduced Fee for Academia and Full Government	EUR 775.00 plus 23% VAT EUR 178.25 HRK 5'812,50 plus 23% VAT 1'336,87	TOTAL EUR 953.25 for participants from the EEA <input type="checkbox"/> TOTAL HRK 7'149.37 for participants from Croatia <input type="checkbox"/>

Exchange rate 1 EUR = 7.50 HRK.

Special discount for SME (status confirmed by EMA) available. Multiple course discount available if booked together with following EVMPD course (8-9 September 2011). Please contact Obzor for more information. 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

After reception of your registration, Obzor will send you a confirmation/invoice with details for your payment which should be made by bank transfer.

Bank transfer only:

Payments should be made to:
OBZOR PUTOVANJA d.o.o.
Teslina 5
10000 Zagreb
Croatia

Payments of participants from the EEA shall be made in EURO to:

ZAGREBACKA BANKA ZAGREB
2360000 - 1000000013 - 2500 - 0490555 - 978
SWIFT CODE ZBAHR2X BY ZAGREBACKA BANKA
IBAN HR3323600001101622374

Payments from Croatian participants shall be made in HRK to

Kunski racun kod PRIVREDNE BANKE ZAGREB 2340009 - 1100182580

Payments should include your name, company, Meeting ID#10578 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 OBZOR office five working days prior to the course start

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Standard EUR 200.00 /HRK 1'500.00 - Reduced EUR 100.00 /HRK 750.00.

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. OBZOR reserves the right to alter the venue and dates if necessary. If an event is cancelled OBZOR 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 OBZOR 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 OBZOR. If you have not received your confirmation within five working days, please contact OBZOR.