EudraVigilance Training
Medicinal Product Dictionary

Course #11587
8-9 September 2011
INFODOM, Zagreb, Croatia

Key Topics that will be covered

- General Terms and Definitions
- EVMPD Data Elements
- Operation Types
- Data Quality
- Data Ownership
- EVMPD Database Architecture
- EVMPD Product Report Database
- EVMPD Scientific Product Database
- EVMPD Product Index Database
- EVMPD and adverse reaction reporting in EudraVigilance
- How to enter and maintain product data in the EVMPD using EVWEB
- Validation process by EMA
- Hands-on experience for examples of different types of medicinal products
- How to query the EVMPD
- Simple Access database

Course Pre-requisites

Participants are expected to have basic background knowledge of:

- EU legislation and guidance documents related to the authorization of medicinal products and the monitoring of safety of clinical trials and post-authorisation pharmacovigilance activities
- Working with a PC

Details of the Course

Duration: 2 days
Location: INFODOM
Andrije Zaje 61/I
10 000 Zagreb, Croatia
Capacity: This course is limited to 18 participants

A Joint Initiative of the European Medicines Agency with DIA acting as a conference organiser

Introduction

The European Medicines Agency (EMA) has prepared the EudraVigilance Medicinal Product Dictionary (EVMPD) course to facilitate the practical implementation of the requirements related to the identification of medicinal products in line with Volume 9A and Volume 10. The population of the EVMPD is necessary to permit the correct identification of medicinal products related to adverse reactions reported in line with the obligations set out in EU legislation. It is also important to support signal detection by the European Medicines Agency and the National Competent Authorities (NCAs) in the EEA and to allow for the implementation of the EudraVigilance Access Policy.

In accordance with Volume 9A, marketing authorisation holders (MAHs) are requested by NCAs and the EMA to enter information on medicinal products, for which they hold a marketing authorization in the EEA, in the EVMPD.
In accordance with Volume 10, Sponsors of clinical trials should enter Investigational Medicinal Products (IMPs) they study in the EVMPD.

Course Overview

This course is the only training programme officially recognised by the EMA. This EVMPD course is addressing specifically all aspects related to the procedures and the technical aspects for the handling and maintenance of medicinal product data in the EVMPD by Sponsors or MAHs. Hands-on experience will be provided based on different medicinal product examples.
Participants that pass the competency assessment following the course will receive a certificate which is a prerequisite to register with EudraVigilance and to enter and maintain medicinal product data in the EVMPD.

Course Goals

At the conclusion of this course, participants should be able to:
- Understand the concepts related to the identification of medicinal products in the EVMPD
- Familiarise with the general terms and definitions related to IMPs and authorised medicinal products
- Describe the data elements of the EVMPD
- Understand and apply medicinal product data entry conventions
- Use the EVWEB application to enter and send medicinal product data in the EVMPD
- Maintain the product information where updates are necessary
- Access and query the EVMPD data using the EVWEB application

Course Audience

The EudraVigilance Medicinal Product Dictionary training programme is targeting personnel of MAHs, sponsors of clinical trials, Contract Research Organisations (CROs), consultants and other organisations that are likely to be involved in submission and maintenance of medicinal product information to the EVMPD.

EudraVigilance

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance Medicinal Product Dictionary Course Agenda

DAY ONE

09:00 **Session 1**
Course Introduction
Introduction to EudraVigilance

Session 2
Regulatory Background
General Terms and Definitions
EVMPD Data Set
Operation Types
Data Quality
Data Ownership

10:30 **Coffee break**

11:00 **Session 3**
Database Architecture
Roles of the EVMPD within the EV System
Data Collection Process

12:30 **Lunch**

13:30 **Session 4**
How to enter product data in the EVMPD using the EVWEB tool
Examples of different types of medicinal products

15:30 **Coffee break**

Session 4 continued

17:30 **END OF DAY ONE**

DAY TWO

09:00 **Session 5**
How to maintain product data in the EVMPD using the EVWEB tool

10:30 **Coffee break**

11:00 **Session 6**
How to perform simple and advanced queries in the EVMPD using the EVWEB tool

12:30 **Sandwich Lunch**

13:30 **Competency Assessment**
Part 1: Multiple Choice Questions
Part 2: Product Report Exam Case

16:30 **END OF DAY TWO**

Course Information

The course will take place at:
INFODOM
Andrije Zaje 61/I
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

Upcoming Courses in Safety and PharmacoVigilance

Benefit/Risk Management
19-20 May 2011 | Prague, Czech Republic | ID 11562

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing
3-7 October 2011 | Zagreb, Croatia | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections
10-11 May 2011 | Amsterdam, The Netherlands | ID 11542
November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance
9-10 May 2011 | Amsterdam, The Netherlands | ID 11543
November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs
19-20 September 2011 | Paris, France | ID 11530

Practical Guide for Pharmacovigilance: Clinical Trials and Post-Marketing
16-18 May 2011 | Nice, France | ID 11527

Pre-Marketing Clinical Safety
4 April 2011 | Basel, Switzerland | ID 11565

DSURs Information Day at the European Medicines Agency
23 March 2011 | London, United Kingdom | ID 11579

EudraVigilance Information Day at the European Medicines Agency
10 May 2011 | London, United Kingdom | ID 11520
15 November 2011 | London, United Kingdom | ID 11522

IDMP Information Day at the European Medicines Agency
16 September 2011 | London, United Kingdom | ID 11524

REGISTRATION FORM

EudraVigilance – Medicinal Product Dictionary
8-9 September 2011 | INFODOM, Zagreb, Croatia

ID # 11587

DIA www.diahome.org

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, lunches and refreshments. The course may be cancelled if numbers of participants are not sufficient.

Standard Fee:	EUR 1050.00 HRK 7'875.00	plus 23%VAT EUR 241.50 plus 23% VAT HRK 1'811.25	**TOTAL EUR 1'291.50 for participant from the EEA** ❑ **TOTAL HRK 9'686.25 for participants from Croatia** ❑
Reduced Fee for Academia and Full Government	EUR 525.00 HRK 3'937.50	plus 23% VAT EUR 120.75 plus 23% VAT 905.63 HRK	**TOTAL EUR 645.75 for participants from the EEA** ❑ **TOTAL HRK 4'843.13 for participants from Croatia** ❑

Special discount for SME (status confirmed by EMA) available. Multiple course discount available if booked together with the EV course (5-7 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 ZABAHR2X 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#10587 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.