# eXtended EudraVigilance Medicinal Product Dictionary Training Course

## Two day training course including hands-on exercises

## Key Topics

- General Terms and Definitions
- Registration in EudraVigilance and Qualified Person Responsible for Pharmacovigilance (QPPV) registration (incl. sponsor registration)
- XEVPRM XSD Schema
- XEVPRM data elements and examples including hands-on exercises
- Operation Types
- Data Quality
- Data Ownership
- XEVMPD technical validation rules
- Use of Controlled Vocabularies

## Course Goals

At the end of this course, participants should be able to:

- Understand the concepts related to the electronic submission of information on medicines authorised in the EU
- Describe the format and the data elements of the XEVPRM for authorised medicinal products
- Discuss practical examples of different types of medicinal products
- Get hands-on experience in working with the XEVMPD
- Describe the format and the data elements of the XEVPRM for IMPs

## Details of the face-to-face training courses:

Duration: 2 days
Location: European Medicines Agency (EMA)
Canary Wharf, 7 Westferry Circus
London E14 4HB, UK

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

## Training on electronic submission of information on medicines New pharmacovigilance legislation (Art. 57, paragraph 2, 2nd sub-paragraph, Regulation (EC) No. 726/2004)

### Introduction

The European Medicines Agency (EMA) is implementing the electronic submission of information on medicines in the context of the new pharmacovigilance legislation (Art. 57, paragraph 2, 2nd sub-paragraph,Regulation (EC) No. 726/2004). On 05 March 2012, EMA published an updated set of mandatory requirements for marketing authorisation holders to comply with Article 57(2). The number of data fields initially required in the format published on 2 July 2011 was considerably reduced, thus significantly reducing the administrative burden and helping marketing authorisation holders to meet their legal deadline of 2 July 2012.

With regard to investigational medicinal products (IMPs), EMA is also facilitating the implementation of the provisions set out in the detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ("CT-3", chapter 7.9, paragraph 104).

### Course Overview

The EMA has prepared this eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) course to facilitate the practical implementation of the requirements including technical aspects and all related procedures on electronic submission of information on medicines by marketing authorisation holders in the European Union (EU).

The training focuses on explaining the guidance, specifically the mandatory data elements necessary for the electronic submission of information on medicinal products applying the format of the eXtended EudraVigilance Product Report Message (XEVPRM) and the use of the XEVMPD data entry tool also known as EVWEB.

Participants who successfully pass the knowledge evaluation following the course will receive a notification from the European Medicines Agency that will allow them to register with EudraVigilance for the electronic submission of information on medicines in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004.

The course also includes instructions for sponsors of clinical trials as how to provide information on the IMPs in the EudraVigilance Medicinal Product Dictionary ('EVMPD') before completing the clinical trials application form.

### Course Audience

The XEVMPD training programme is targeting personnel of marketing authorisation holders, consultants and other organisations, who are responsible for the electronic submission and maintenance of information on medicinal products authorised in the EU.
It is also targeting sponsors of clinical trials responsible for providing information on IMPs in accordance with the CT-3 detailed guideline.

**The content of this training course is subject to regular updates in order to comply with new regulations and requirements.**

[1]http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000492.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058033e8ad&jsenabled=true

EudraVigilance

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## What this course offers

- Training in meeting the requirements of the provisions of Article 57(2), second sub-paragraph of Regulation (EC) 726/2004 and the electronic submission of information on authorised medicinal products
- Training in supporting the electronic submission of information on authorised medicinal products for Gateway users
- Training in developing messages compliant with the published XEVPRM XSD schemas
- Training in supporting the electronic submission of information on authorised medicinal products for Web trader and XEVMPD users
- Hands-on training using the XEVMPD to generate XEVPRMs
- Training in meeting the requirements of the provisions set out in the detailed guidance ("CT-3") and the electronic submission of information on IMPs

## What this course does not cover

- Training in developing and validating information or communication technology tools to produce messages compliant with the published XEVPRM and SSI XSD schemas
- Training on all five ISO Identification of Medicinal Products (IDMP) standards and the Individual Case Safety Report (ICSR) standard as well as related ICH Implementation Guides
- Training on IDMP, ICSR and Common Product Model (CPM) HL7 V3 messages

## Course Pre-requisites

Participants are expected to have basic background knowledge of:

- EU legislation and the revised guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the European Medicines Agency in accordance with Article 57 (2), second subparagraph of Regulation (EC) 726/2004
- Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ("CT-3", cahpter 7.9, pragraph 104).

## Hotel Information

Attendees have to make their own reservation.

Recommended hotel close to the EMA:
**Hilton London Docklands Riverside**
265 Rotherhithe Street,
London , SE16 5HW,
United Kingdom

Telephone: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: reservations.docklands@hilton.com

Special negotiate rate for participants to the EudraVigilance training course for a limited number of rooms is GBP 139.00 per room (2013 rate) incl. breakfast excl. VAT.

The hotel is situated opposite of Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance to the EMA (2 min).



## DIA Upcoming Training Courses in Safety and Pharmacovigilance

- **Benefit/Risk Management**
  Next recurrence of this course to be announced
- **Diagnosis and Management of Drug-Induced Liver Injury (DILI)**
  Next recurrence of this course to be announced
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  7–8 November 2013 | Paris, France | ID 13556
- **ICH Endorsed Pharmacovigilance**
  28-29 November 2013 | Zagreb, Croatia | ID 13569
- **Pre-Marketing Clinical Safety**
  Next recurrence of this course to be announced
- **Signal Management in Pharmacovigilance**
  6–7 November 2013 | Paris, France | ID 13558

### European Medicines Agency Information Days and Courses

- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  18-22 November 2013 | London, United Kingdom | ID 13522
  17-21 February 2014 | London, United Kingdom | ID 14500
- **MedDRA Information Day**
  22 October 2013 | London, United Kingdom | ID 13542
- **EudraVigilance Information Day**
  10 December 2013 | London, United Kingdom | ID 13530
- **EudraVigilance courses:**
  - EudraVigilance – Electronic reporting of ICSRs in the EEA
  - 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.

# Course Agenda

## DAY ONE

**8:45 Session 1**

Course Introduction
Introduction to EudraVigilance
Registration to EudraVigilance

**Session 2**

Regulatory Background
General Terms and Definitions
eXtended EudraVigilance Medicinal Product Report Message (XEVMPRM) Data Set
Operation Types
Data Quality
Data Ownership

**Session 3**

Database Architecture
Roles of the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) within EudraVigilance
Data Collection Process

COFFEE BREAK

**Session 4**

How to enter product data in the XEVMPD using the EVWEB tool
How to enter an organisation (MAH and Sponsor)
How to enter a substance (an approved and a development substance), translations and synonyms

LUNCH

**Session 4 continued**

Examples of different types of authorised medicinal products
- Nationally authorised medicinal product
- Medicinal product authorised through the mutual recognition procedure
- Centrally authorised medicinal product

Investigational Medicinal Product (Development Medicinal Product) for sponsors of clinical trials

17:45 END OF DAY ONE

## DAY TWO

**8:45 Session 5**

How to perform simple and advanced queries in the XEVMPD using the EudraVigilance Web-based application (EVWEB)

**Session 6**

How to maintain product data in the XEVMPD using EVWEB
How to use the operation type “withdraw” for an authorised medicinal product

COFFEE BREAK

Example how to use the operation type “update” for substance (including the handling of translations and synonyms)
Example how to use the operation type “update” for an organisation

SANDWICH LUNCH

Knowledge Evaluation
Part 1: Multiple Choice Questions
Part 2: Product Report Exam Case

17:00 END OF DAY TWO

The Agenda is subject to change as course content is updated regularly in order to comply with new regulations and requirements.

# REGISTRATION FORM

eXtended EudraVigilance Medicinal Product Dictionary Training Course
European Medicines Agency, London, UK

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

## FEES

| | | | |
|---|---|---|---|
| Standard Fee | € | 1'180.00 | ❑ |
| Reduced Fee for Academia/Non-profit (Full-time) | € | 585.00 | ❑ |
| Reduced Fee for Government | € | 525.00 | ❑ |

Special discount - for SME (status confirmed by EMA) available. Multiple course discount available if booked together with the three day EudraVigilance training course.

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.

I wish to attend the following course in 2013:

| 1st | 2nd choice | | |
|---|---|---|---|
| ❑ | ❑ | 06 – 07 February 2014 | 14529 |
| ❑ | ❑ | 10 – 11 March 2014 | 14525 |
| ❑ | ❑ | 22 – 23 May 2014 | 14526 |

## 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:

- Industry € 200.00.
- Academia/Charitable/Government /Non-profit (Full-time) € 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.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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