eXtended EudraVigilance Medicinal Product Dictionary
Face-to-face training course

Duration: 1.5 days

Location: European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
E14 5EU London, UK

OVERVIEW

The submission of data on medicines by marketing-authorisation holders is a legal requirement from Article 57(2) of Regulation (EC) No. 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012.

The EMA has prepared this eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) face-to-face training 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) and European Economic Area (EEA) countries outside the EU.

The training focuses on explaining the guidance and 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 (EVWEB). It includes exercises in the XEVPRM data entry tool (EVWEB) for the electronic submission and maintenance of different types of medicinal products.

Participants who successfully pass the knowledge evaluation following the training course will receive a notification of successful completion of this training course from the European Medicines Agency that will allow them to register with EudraVigilance for the electronic submission of information on medicinal products. At least one user from each marketing-authorisation holder organisation should receive training. The aim is to ensure the quality of data submitted to the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD).

The course also includes instructions for sponsors of clinical trials on how to provide information on Investigational Medicinal Products (IMPs) in the medicinal product dictionary before completing the clinical trials application form.

LEARNING OBJECTIVES

At the conclusion of this training course participants will be able to:

- Understand the legal requirements for marketing authorisation holders to comply with the provisions set out in Article 57(2) of Regulation (EC) 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012
- Understand the requirements for sponsors of clinical trials as outlined 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') (OJ 2011/C 172/01)
- Be familiar with the eXtended EudraVigilance Product Report Message (XEVPRM) format used for the electronic submission of information on authorised medicinal products as well as investigational medicinal products.
- Understand the controlled vocabularies and terminologies to be used during the submission process
- Use the XEVPRM data entry tool (EVWEB) for the electronic submission and maintenance of different types of medicinal products
- Explain the data structure of the eXtended EudraVigilance Product Dictionary (XEVMPD) for data entry and data retrieval
- Understand the importance of the XEVMPD to support the pharmacovigilance activities in the EU

TARGET AUDIENCE

The XEVMPD training programme is intended for 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.

The programme content is also geared towards sponsors of clinical trials responsible for providing information on IMPs in accordance with the CT-3 detailed guideline 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).**

*http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b&jsenabled=true#section7

**http://ec.europa.eu/health/files/eudralex/vol-10/2011_c172_01/2011_c172_01_en.pdf

COURSE DATES:

21-22 April 2016 #16515

16-17 June 2016 #16516

20-21 October 2016 #16596

17-18 November 2016 #16597

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance

DIA DEVELOP INNOVATE ADVANCE

DAY ONE

11:00 Session 1
Introduction & Registration to EudraVigilance

- Course Introduction
- Introduction to EudraVigilance
- Registration to EudraVigilance

Session 2 - Theoretical Background

- Regulatory Background
- General Terms and Definitions

13:00 LUNCH BREAK

14:00 Session 2 Theoretical Background cont.

- Operation Types
- Data Quality
- Data Ownership

Session 3 - Creation of different Product Message Reports (XEVPRMs)

Practical Exercises in the EVWEB with Operation type "insert"

- Insert of a Marketing Authorisation Holder (MAH) and a Sponsor
- Insert of a Masterfile location (MFL)

15:30 COFFEE BREAK

16:00 Session 3 - Creation of different Product Message Reports (XEVPRMs)

Practical Exercises in the EVWEB with Operation type "insert"

- Insert of an Authorised Medicinal Product (AMP)
- Validation and Sending of a XEVPRM
- Practical Exercise on how to view and retrieve a XEVPRM Acknowledgement (XEVPRM ACK)

17:45 End of Day One

COURSE PREREQUISITIES

Participants are expected to have basic background knowledge of the EU legislation and be familiar with guidance documents published by the EMA*, specifically:

- Detailed 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) of Regulation (EC) No. 726/2004 / Chapter 3.II: XEVPRM User Guidance
- Legal Notice on the Implementation of Article 57(2) of Regulation (EC) No. 726/2004
- Electronic submission of Article 57(2) data - Questions & Answers (Q&As)

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 DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

DAY TWO

08:30 Session 3 - Creation of different Product Message Reports (XEVPRMs)

Practical Exercises in the EVWEB with Operation type "insert"

- Insert of a development medicinal product (DMP)

Session 4 - XEVMPD Simple and Advanced Queries and Maintenance Operations

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

Maintenance Operations – Operation type UPDATE

- Practical exercise on how to use the operation type "update" for an organisation
- Practical exercise on how to use the operation type "update" for a change in procedure
- Example how to use the operation type "Invalidate MA" for an Authorised Medicinal Product

10:30 COFFEE BREAK

11:00 Knowledge Evaluation

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

13:00 End of Day Two

WHAT THIS COURSE OFFERS

- Training in meeting the requirements of the provisions set out in Article 57(2) of Regulation (EC) 726/2004, as amended by Regulation (EU) 1235/2010
- 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

REGISTRATION FORM

eXtended EudraVigilance Medicinal Product Dictionary Face-to-face training course
European Medicines Agency (EMA), London, UK
Please register online at www.diaglobal.org/EudraVigilance

REGISTRATION FEES

Registration fee includes IT equipment, refreshment breaks, lunch and training course material.

FEES	
STANDARD	€ 980.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 485.00 ❑

Special discount - for SME (status confirmed by EMA) on standard registration fee available. Please contact DIA for more information.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

I wish to attend the following course in 2016:

1st 2nd choice

❑ ❑ 21-22 April 2016 #16515

❑ ❑ 16-17 June 2016 #16516

❑ ❑ 20-21 October 2016 #16596

❑ ❑ 17-18 November 2016 #16597

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51 Fax: +41 61 225 51 52

Email: EMEA@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.
DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA 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 - for the same course - to a colleague of the same organisation. Please notify the DIA office of such a substitution as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

ATTENDEE DETAILS:

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number Fax Number

email (Required for confirmation)

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, Course 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, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature