

eXtended EudraVigilance Medicinal Product Dictionary

Face-to-face training course

Course #15527

02-03 March 2015

Agencia Espanola Medicamentos y Productos Sanitarios (AEMPS), Spain

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 (XEVMPPD) 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 XEVMPPD 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 (XEVMPPD).

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

LEARNING OBJECTIVES

At the conclusion of this training course participants should 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 (XEVMPPD) for data entry and data retrieval
- Understand the importance of the XEVMPPD to support the pharmacovigilance activities in the EU

TARGET AUDIENCE

The XEVMPPD 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 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 LOCATION

Agencia Espanola Medicamentos y
Productos Sanitarios (AEMPS)
Parque Empresarial Las Mercedes
Edificio 8
1 Campezo Street
28022 Madrid
Spain



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance

DIA DEVELOP
INNOVATE
ADVANCE

DAY ONE

9:00 Session 1

- Course Introduction
- Introduction to EudraVigilance
- Registration to EudraVigilance

Session 2

- Regulatory Background
- General Terms and Definitions

11:00 COFFEE BREAK

Session 2 continued

- Operation Types
- Data Quality
- Data Ownership

Session 3

Practical Exercises on how to enter product data in the XEVMPD using the EVWEB on Operation type INSERT of

- An Organisation: Marketing Authorisation Holder (MAH) and a Sponsor organisation
- A Masterfile location (MFL)

13:00 LUNCH BREAK

14:00 Session 3 continued

Practical Exercises on how to enter product data in the XEVMPD using the EVWEB on Operation type INSERT of

- An Authorised Medicinal Product (AMP)

15:30 COFFEE BREAK

Session 3 continued

Practical Exercises on how to enter product data in the XEVMPD using the EVWEB on Operation type INSERT of

- An Authorised Medicinal Product (AMP):
- How to validate and send a xEVPRM?

Practical Exercise on how to view and retrieve a XEVPRM Acknowledgement (XEVPRM ACK)

Practical Exercises on how to enter product data in the XEVMPD using the EVWEB on Operation type INSERT of

- A development medicinal product

DAY TWO

9:00 Review on entering product data in the XEVMPD with Operation type INSERT

9:30 Session 4

Maintenance Operations - Additional practical exercises
How to perform simple and advanced queries in the XEVMPD using the EudraVigilance Web-based application (EVWEB)

Session 5

Maintenance Operations - Additional practical exercises
Example how to use the operation type “update” for an organisation
Example how to use the operation type “update” for a change in procedure

11:00 COFFEE BREAK

Example how to use the operation type “Invalidate MA” for an Authorised Medicinal Product

13:00 SANDWICH LUNCH

14:00 Knowledge Evaluation

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

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

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.

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)

REGISTRATION FORM

eXtended EudraVigilance Medicinal Product Dictionary Face-to-face training course #15527
02-03 March 2015 | Agencia Espanola Medicamentos y Productos Sanitarios (AEMPS), Spain

REGISTRATION FEES

Registration fee includes IT equipment, refreshment breaks, lunches and training course material. Please check:

FEES	
STANDARD	€ 1'180.00 □
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 585.00 □

All fees will be subject to the Spanish VAT at 10%

Please enter your Company's Spanish VAT number: _____

Special discount - for SME (status confirmed by EMA) 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.

The DIA Europe, Middle East and 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: diaeurope@diaeurope.org Mail: DIA EMEA, Küchengasse 16, 4051 Basel, Switzerland

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office five working days 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
- Tutorial cancellation € 50.00

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.

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Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions 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 15527 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.**

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Date

Signature