VIRTUAL EVENT

eXtended EudraVigilance Medicinal Product Dictionary Training Course

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) virtual live 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 XEVMPD 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 per Article 81(3) of CT Regulation (EU) No 536/2014
- 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 XEVMPD 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

COURSE DATES AND TIME:

Course #25580
10-12 February 2025
09:00 - 13:30 CET

Course #25581
09-11 April 2025
14:00 - 18:30 CEST

Course #25582
18-20 June 2025
09:00 - 13:30 CEST

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 Article 81(3) of CT Regulation (EU) No 536/2014.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

On demand content

These topics are offered on demand and should be completed before joining the live course:

Session 2 - Theoretical Background

- *General Terms and Definitions*

Session 6 - Support Options

Day 1 - Module 1

09:00 Or 14:00

Course Introduction

Session 1

- Introduction to EudraVigilance, XEVMPD and roles of XEVMPD within EudraVigilance
- Registration with EudraVigilance
- XEVMPD submission tools and XEVMPRM Acknowledgements

Session 2

- Regulatory Requirements

10:30 Or 15:30

Break

11:00 Or 16:00

Session 2 continued

- ISO IDMP implementation
- Data Ownership
- Available Operation Types
- XEVMPD submission processes
- Data Quality

13:00 Or 18:00

Technical Check

- Practical Exercises: Creation of different Product Message Reports (XEVPRMs) in the EVWEB with Operation type "insert"
  - Insert of a Marketing Authorisation Holder (MAH) and a Sponsor
  - Insert of a Masterfile location (MFL)

13:30 Or 18:30

End of Day 1

Day 2 - Module 2

09:00 Or 14:00

Session 3 - Operation Type Insert

Session 4 - Theoretical Background and Practical Exercises: Creation of different Product Message Reports (XEVPRMs) in the EVWEB with Operation type "insert"

This part will be performed in smaller breakout groups. A 30-minute break is foreseen in-between.

- Insert of a development medicinal product (DMP)
- 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)

13:30 Or 18:30

End of Day 2

Day 3 - Module 3

09:00 Or 14:00

Session 5 - 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

11:00 Or 16:00

Break

11:30 Or 16:30

Knowledge Evaluation

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

13:30 Or 18:30

End of Day 3

COURSE PREREQUISITIES

Participants are expected to have:

- Requested access to the training environment as per instructions provided upon registration
- Completed technical setup and have ActiveX and IE Tab extension installed on their computers before the start of the training course, as per instructions provided upon registration
- Basic background knowledge of the EU legislation and be familiar with guidance documents published by the EMA, specifically Chapter 3.II: XEVPRM User Guidance of the 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

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 for sponsors of clinical trials as per Article 81(3) of CT Regulation (EU) No 536/2014

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