VIRTUAL EVENT

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Training Course

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview

Submitting medicinal product data is a legal requirement for marketing authorisation holders under Article 57(2) of Regulation (EC) No. 726/2004 and its amendments.

The EMA's XEVMPD virtual live training supports the practical and technical implementation of these requirements for electronic submissions in the EU and EEA.
The course explains the guidance and mandatory data elements for electronic submissions using the eXtended EudraVigilance Product Report Message (XEVPRM) format and XEVMPDweb, with hands-on exercises for submitting and maintaining product data.

Participants who pass the knowledge evaluation receive EMA notification enabling registration with EudraVigilance for electronic submissions of medicinal product data. Each marketing authorisation holder should have at least one trained user to ensure data quality.

The course also guides clinical trial sponsors on submitting Investigational Medicinal Product (IMP) data before completing clinical trial application application.

Course Pre-requisites

For this training course, participants:

- Need an active EMA account for the practical exercises in the XEVMPDweb test environment (XCOMP).
- Have a good command of the English language and be proficient in using a computer and Zoom to participate effectively in the course.
- Are expected to have basic background knowledge of the EU legislation and be familiar with guidance documents published by the EMA, specifically Article 57(2) of Regulation (EC) 726/2004 and its amendments for marketing authorisation holders and Article 81(3) of CT Regulation (EU) No 536/2014 on providing information on IMPs for sponsors of clinical trials.

Further information on the EudraVigilance system training can be found on the dedicated EMA EudraVigilance training page.

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 Regulations (EU) 1235/2010 and (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 and investigational medicinal products.
- Understand the controlled vocabularies and terminologies to be used during the submission process.
- Use the XEVMPDweb for the electronic submission and maintenance of different types of medicinal products.
- Explain the data structure of the XEVMPDweb for data entry and data retrieval.
- Understand the importance of the XEVMPD to support the pharmacovigilance activities in the EU.

COURSE DATES & TIME (CET)

- 11-13 March 2026 - 09:00 - 13:30, # 26580
- 22-24 April 2026 - 14:00 - 18:30, # 26581
- 22-24 June 2026 - 09:00 - 13:30, # 26582

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.

BENEFITS OF ATTENDING

- Understand requirements of Article 57(2) of Regulation (EC) 726/2004 (as amended).
- Support electronic submission of authorised medicinal product data (Gateway & Web Trader users).
- Create messages compliant with XEVPRM XSD schemas.
- Gain hands-on experience generating XEVPRMs in XEVMPDweb.
- Learn requirements for clinical trial sponsors under Article 81(3) of Regulation (EU) 536/2014.

DIA

AGENDA (Timing in CE(S)T)

DAY 1 Module 1

09:00 or 14:00 - Start of Day 1

Introduction

Session 1

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

Session 2

- Regulatory Requirements

10:30 Or 15:30 Break

11.00 Or 16:00 - Session 2 continued

- ISO IDMP implementation
- General terms and definitions
- Data Ownership
- Available Operation Types
- XEVMPD submission processes
- Data Quality

13:00 Or 18:00 - Technical Check

- Log into XEVMPDweb

- Insert of a Marketing Authorisation Holder (MAH) and a Sponsor
- Insert of a Master File Location (MFL)

13:30 or 18:30 - End of Day 1

DAY 2 Module 2

09:00 Or 14:00 - Start of Day 2

Session 3 - Operation Type 'Insert'
Session 4: Acknowledgements
Theoretical Background and Practical Exercises:
After the theoretical background, the practical exercises will be performed in smaller breakout groups.
A 30-minute break is foreseen in-between.

- Insert of an Authorised Medicinal Product (AMP)
- Insert of a Development medicinal product (DMP)
- Validate and send an XEVPRM,
- View and retrieve an XEVPRM Acknowledgement (XEVPRM ACK)

13:30 Or 18:30 - End of Day 2

DAY 3 Module 3

09:00 Or 14:00 - Start of Day 3

Session 5 - XEVMPD Simple and Advanced Queries

- Perform simple and advanced queries in the XEVMPDweb

Session 6 - Maintenance operations
Theoretical Background and Practical Exercises /Demonstrations:

- Apply operation type 'Update' for MAHs and sponsors
- Apply operation type 'Nullification'
- Apply operation type 'Invalidate MA'

11:00 Or 16:00 Break

11:30 Or 16:30 - KNOWLEDGE EVALUALUATION

Part 1: Multiple Choice Questions

Part 2: Product Report Exam Case*

*this part needs to be completed during this session.

13:30 or 18:30 - End of Day 3

What Is Not Covered

- 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.

On Demand Content

This topic is offered on demand and should be completed before joining the live course: Session 6 - Support Options