VIRTUAL EVENT

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Training Course For Sponsors

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Overview

Commercial and non-commercial sponsors of clinical trials are responsible for providing information on Investigational Medicinal Products (IMPs) referred to as Development Medicinal Products (DMPs) in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) in accordance with Article 81(3) of CT Regulation (EU) No 536/2014.

This EMA 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 the 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. Each sponsor should have at least one trained user to ensure data quality.

Course Pre-requisites

For this training course, participants:

- Need an active EMA account for the practical exercises in the XEVMPD 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 a basic knowledge of the EU legislation for clinical trials specifically with Article 81(3) of CT Regulation (EU) No 536/2014 on providing information on IMPs.

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 requirements for sponsors of clinical trials as per Article 81(3) of CT Regulation (EU) No 536/2014.
- ·Use the format for electronic submission of information on 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 DMPs;
- ·Understand the data structure of the XEVMPDweb for data entry and data retrieval;
- Understand the importance of the XEVMPD to support the submission of clinical trial information in the Clinical Trials Information System (CTIS).

COURSE DATES & TIME (CET)

- 03-04 November 2026 - 09:00 - 13:30, # 26588

TARGET AUDIENCE

This XEVMPD training programme is intended for commercial and non-commercial 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 set out in Article 81(3) of CT Regulation (EU) No 536/2014
- Create messages compliant with XEVPRM XSD schemas.
- Support electronic submission of information on development medicinal products via the XEVMPD Data entry tool.
- Gain hands-on experience generating XEVPRMs in XEVMPD.web

DIA

AGENDA (Timing in CE(S)T)

DAY 1 Module 1

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

Welcome & Introduction

Session 1

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

11:00 or 16:00 BREAK (30 min)

Session 2

- Regulatory Requirements
- ISO IDMP Implementation
- General Terms and Definitions
- Data Ownership
- Available Operation Types
- XEVMPD submission processes
- Data Quality

13:00 or 18:00 - Technical Check & practical exercise

- Login to XEVMPDweb
- Insert of a Sponsor organisation

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

On Demand Content

This topic is offered on demand and should be completed before joining the live course for any follow up questions:

- Support Options for XEVMPD submissions

DAY 2 Module 2

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

Session 3 - Operation Type 'Insert'

Session 4 - Acknowledgements

Session 5 - Updates

Session 6 - Nullification

Theoretical background, practical exercises & demo

After the theoretical background, the practical exercises will be performed in smaller groups:

Exercises:

- Insert of a development medicinal product (DMP)
- Validation and sending of an XEVPRM

Demonstration on:

- How to view and retrieve an XEVPRM Acknowledgement (XEVPRM ACK)
- How to perform simple queries in the XEVMPD
- How to apply operation types 'Update' & 'Nullification'

11:00 or 16:00 BREAK (30 min)

11:30 Or 16:30 KNOWLEDGE EVALUATION

- 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 This Training Course

WHAT IS NOT COVERED

- Training on how to submit SUSARs
- Training on the Clinical Trial Information System (CTIS)
- Training on MedDRA
- Training in developing and validating information or communication technology tools to produce messages compliant with the published XEVPRM and SSI XSD schemas
- Training on IDMP, ICSR and Common Product Model (CPM) HL7 V3 messages