eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Live Virtual Training Course for Sponsors

| COURSE DATES AND TIME

Course # 25586
13-14 March 2025
09:00 – 13:30CET

Course # 25587
26-27 May 2025
14:00 - 18:30 CEST

| TARGET AUDIENCE

This XEVMPD training programme is intended for commercial and non-commercial sponsors of clinical trials.

| COURSE PREREQUISITES

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 for clinical trials specifically with Article 81(3) of CT Regulation (EU) No 536/2014 on providing information on IMPs

| OVERVIEW

Sponsors of clinical trials are responsible for providing information on Investigational Medicinal Products (IMPs) in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) in accordance with Article 81(3) of CT Regulation (EU) No 536/2014.
The EMA has prepared this live virtual training course to facilitate the practical implementation of the requirements including technical aspects and all related procedures on electronic submission of information on un-authorised referred to in the XEVMPD as development medicinal products (DMPs) by commercial and non-commercial sponsors of clinical trials in the European Economic Area (EEA).

The training focuses on explaining the guidance and mandatory data elements necessary for the electronic submission of information on development 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 practical exercises in EVWEB for the electronic submission and maintenance of development medicinal product information.

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. This notification is requested from at least one user from the sponsor organisation during the organisation's registration with EudraVigilance for the electronic submission of information on DMPs. The aim is to ensure the quality of data submitted to the XEVMPD.

| 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 XEVPRM data entry tool (EVWEB) for the electronic submission and maintenance of DMPs;
- Understand the data structure of the XEVMPD 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).

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AGENDA | TIMING IN CE(S)T	The timing in the agenda refer to both morning and afternoon courses

\| 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

Morning/Afternoon – DAY 1

09:00 OR 14:00 WELCOME & INTRODUCTION

SESSION 1

- Introduction to EudraVigilance
- Introduction to XEVMPD & the roles of XEVMPD within EudraVigilance
- Registration with EudraVigilance
- XEVMPD submission tools and acknowledgements

11:00 OR 16:00 BREAK (30 MIN)

SESSION 2

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

SESSION 3

- Operation Type Insert

13:00 OR 18:00 Practical exercise on Operation type "insert" and technical check

- Insert of a Sponsor organisation

13:30 OR 18:30 END OF DAY 1

Morning/Afternoon – DAY 2

09:00 OR 14:00 START OF DAY 2

SESSION 4

- Introduction to the XEVMPD data entry tool and creation of product message reports (XEVPRM) in EVWEB with operation type "insert"
  - 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)
- Performing simple queries in the XEVMPD
- Maintenance Operation type: UPDATE and NULLIFY

11:00 OR 16:00 BREAK

11:30 or 16:30 KNOWLEDGE EVALUATION

- Part I – Multiple Choice Questions
- Part II – Product Report Exam Case

13:30 OR 18:30 END OF THIS TRAINING COURSE

\| WHAT THIS COURSE OFFERS

- Training in creating messages compliant with the published XEVPRM XSD schemas
- Training in the electronic submission of information on development medicinal products via the XEVMPD Data entry tool.
- Hands-on training using the XEVMPD to generate XEVPRMs
- Training in meeting the requirements set out in Article 81(3) of CT Regulation (EU) No 536/2014

\| WHAT THIS COURSE DOES NOT OFFER

- 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