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) 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 XEVMPD 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 (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 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 (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 #22580
14-16 February 2022
14:00 - 18:00 CET

Course #22581
2-4 May 2022
9:00 - 13:00 CEST

Course #22582
27-29 June 2022
14:00 - 18:00 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 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).

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

Day 1 - Module 1

09:00 Or 14:00 CET

Course Introduction

Session 1- Introduction & Registration to EudraVigilance

- Introduction to EudraVigilance
- Registration to EudraVigilance

Session 2 - Theoretical Background

- Regulatory Background
- General Terms and Definitions
- Operation Types
- Data Quality
- Data Ownership

Session 3 - Practical Exercises of creation of different Product Message Reports (XEVPRMs) and insert of a development medicinal product (DMP)

- Insert of a Marketing Authorisation Holder (MAH) and a Sponsor
- Insert of a Masterfile location (MFL)
- Insert of a development medicinal product (DMP)
- Validation and Sending of a XEVPRM

13:00 or 18:00 CET

End of Day 1

Day 2 - Module 2

09:00 Or 14:00 CET

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

- Insert of an Authorised Medicinal Product (AMP)
- Demonstration on how to view and retrieve a XEVPRM Acknowledgement (XEVPRM ACK)

13:00 or 18:00 CET

End of Day 2

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Day 3 - Module 3

09:00 Or 14:00 CET

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

Knowledge Evaluation

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

13:00 or 18:00 CET

End of Day 3

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)

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 messages