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 #25583
17-19 September 2025
14:00 - 18:30 CEST

Course #25584
20-22 October 2025
09:00 - 13:30 CEST

Course #25585
19-21 November 2025
14:00 - 18:30 CET

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

This topic is offered on demand and should be completed before joining the live course:

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 Article 57(2) of Regulation (EC) 726/2004, as amended by Regulation (EU) 1235/2010 and Regulation (EU) 1027/2012 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
- Attendees must have a strong command of the English language to participate in the course effectively as well as basic knowledge on zoom functionalities

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

REGISTRATION FORM

eXtended EudraVigilance Medicinal Product Dictionary

Virtual training course

You can register online at www.diaglobal.org/EMA/course-listing

REGISTRATION FEES

FEES	
STANDARD	€ 950.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 425.00 ❑

All registration fees are subject to VAT, if applicable.

Please enter your Company's European VAT number:_____

A special discount for SMEs on the standard fee is available for a limited number of places.
To proof your status as an SME, a confirmation of the European Medicines Agency is necessary.

Please provide your SME number here : _____

Payment is due 30 days after registration and must be paid in full by commencement of the course.

Please select one course:

- ❑ Course **#25583:** 17-19 September 2025, 14:00 - 18:30 CEST
- ❑ Course **#25584**: 20-22 October 2025, 09:00 - 13:30 CEST
- ❑ Course **#25585**: 19-21 November 2025, 14:00 - 18:30 CET

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51
Fax: +41 61 225 51 52

Email: basel@DIAglobal.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.DIAglobal.org

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel 28 days prior to the event start date and do not attend, you will be responsible for the full registration fee.

Please note that switching from one course date to another is considered a cancellation and the same policy applies.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration - for the same course - to a colleague of the same organisation. Such a transfer is possible until 5 working days before the start of the training course. Please notify the DIA office of such a substitution as soon as possible.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click https://www.diaglobal.org/general/photography-policy.

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click https://www.diaglobal.org/en/about-us/privacy-policy.

ATTENDEE DETAILS:

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Direct email attendee (Required for course material access)

PAYMENT METHOD

DIA accepts only Credit Card as a payment method.

Payments by VISA, Mastercard or AMEX are accepted. Other types of credit card are not accepted.

You will receive a payment link in the coming days to complete the payment.

Please complete payment within 7 days of receipt of the payment link.

Payments will be net of all charges and bank charges will be borne by the payer.

If you have not received your confirmation within five working days, please contact basel@diaglobal.org**.**

By signing below, I confirm that I read and agree with DIA's Terms and Conditions of booking.

These are available from the office or online by clicking:

http://www.diaglobal.org/EUterms

Date	Signature