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

| COURSE DATES AND TIME

Course # 22589
29-30 September 2022
14:00 - 18:00 CET

Course # 22590
24-25 October 2022
14:00 - 18:00 CET

Course # 22591
14-15 November 2022
09:00 - 13:00 CET

| TARGET AUDIENCE

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

| 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 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 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

| 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 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).

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 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 (DMPs), 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 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 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)
- Use the eXtended EudraVigilance Product Report Message (XEVPRM) format used 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
- 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 submission of clinical trial information in the Clinical Trials Information System (CTIS)

| COURSE PREREQUISITIES

Participants are expected to have basic background knowledge of the EU legislation for clinical trials and be familiar with detailed guidance ("CT-3") and the electronic submission of information on IMPs.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA

AGENDA | TIMING IN CEST

5 May		30 JUNE – DAY 1
09:00	14:00	WELCOME, INTRODUCTION AND TECHNICAL CHECK SESSION 1 INTRODUCTION TO THE EUDRAVIGILANCE SYSTEM • Introduction • EudraVigilance System Components • Gateway • Organisation and User Management • EudraVigilance registration
11:00	16:00	BREAK
11:30	16:30	SESSION 2 – THEORETICAL BACKGROUND • Regulatory Background • General Terms and Definitions • Operation Types • Data Quality • Data Ownership
12:30	17:30	SESSION 3 - EMA SUPPORT OPTIONS (UPDATE EV S16)
12:50	17:50	Q&A
13:00	18:00	END OF DAY 1

6 May		1 July - DAY 2
09:00	14:00	WELCOME
09:10	14:10	SESSION 4 – INTRODUCTION TO THE XEVMPD DATA ENTRY TOOL CREATION OF A PRODUCT MESSAGE REPORT (XEVPRM) IN EVWEB Theoretical background Practical exercise on Operation type "insert": ▪ Insert of a Sponsor organisation ▪ 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 XEVMP ▪ Maintenance Operation type: UPDATE and NULLIFY
11:00	16:00	BREAK
11:30	16:30	Q&A
11:45	16:45	KNOWLEDGE EVALUATION ▪ Part I – Multiple Choice Questions ▪ Part II – Product Report Exam Case
13:00	18:00	END OF THIS TRAINING COURSE

REGISTRATION FORM

eXtended EudraVigilance Medicinal Product Dictionary for Sponsors

virtual training course

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

REGISTRATION FEES

FEES	
STANDARD	€ 710.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 355.00 ❑

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 **#22589**: 29-30 September 2022, 14:00-18:00 CEST
- ❑ Course **#22590**: 24-25 October 2022, 14:00-18:00 CET
- ❑ Course **#22591**: 14-15 November 2022, 09:00-13:00 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 CE(S)T. 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 METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

- **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

- Bank transfers: When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID # as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on http://www.diaglobal.org/EUTerms

Date	Signature