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

| COURSE DATES AND TIME

Course # 24586
29 Feb – 01 Mar 2024
09:00 – 13:00 CET

Course # 24587
12-13 June 2024
09:00 – 13:00 CEST

| TARGET AUDIENCE

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

| 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 for clinical trials and be familiar with detailed guidance ("CT-3") and the electronic submission of 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 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 Medicinal 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).

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AGENDA | TIMING IN CE(S)T

Morning/Afternoon – DAY 1

09:00 OR 14:00 WELCOME & INTRODUCTION

SESSION 1 INTRODUCTION TO THE EUDRAVIGILANCE SYSTEM

- Introduction
- EudraVigilance System Components
- Gateway
- Organisation and User Management
- EudraVigilance registration

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

SESSION 2 – THEORETICAL BACKGROUND

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

SESSION 3 - EMA SUPPORT OPTIONS

12:50 OR 17:50 Q&A

13:00 OR 18:00 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/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 XEVMPD
- Maintenance Operation type: UPDATE and NULLIFY

11:00 OR 16:00 BREAK

11:30 OR 16:30 Q&A

11:45 or 16:45 KNOWLEDGE EVALUATION

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

13:00 OR 18:00 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 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