Extended EudraVigilance Medicinal Product Dictionary Training Courses

Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Training on electronic submission of information on medicines
New pharmacovigilance legislation (Art. 57, paragraph 2, 2nd subparagraph, Regulation (EC) No. 726/2004)

European Medicines Agency
Canary Wharf, 7 Westferry Circus | London E14 4HB, UK

Key Topics

- General Terms and Definitions
- Registration in EV and QPPV registration
- XEVPRM XSD Schema
- XEVPRM data elements and examples
- XEVPRM and Structured Substance Information including examples of various substance classes
- Operation Types
- Data Ownership
- XEVMPD technical validation rules
- Use of Controlled Vocabularies

What this course offers:

- Training in meeting the requirements in the provisions of Article 57(2), second sub-paragraph and in the electronic submission of information on medicines
- Training in supporting the electronic submission of medicinal product information for Gateway users
- Training in supporting the electronic submission of medicinal product information for Web trader users[2]
- Training in developing messages compliant with the published XEVPRM and Structured Substance Information (SSI) XSD schemas
- Training on the tools developed by the European Medicines Agency to generate XEVPRM and SSI messages (this course module is scheduled to be available as of February 2012)

[2]For Web Trader users and EVWEB users further guidance will be released in February 2012 when the data entry tools will be made available by the European Medicines Agency

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 messages

A joint initiative of the European Medicines Agency with DIA acting as a conference organiser

Introduction

The European Medicines Agency (EMA) is implementing the electronic submission of information on medicines in the context of the new pharmacovigilance legislation[1]. As required by this legislation, the Agency has published the format for the electronic submission of information on medicinal products for human use on 1 July 2011. Marketing authorisation holders need to submit electronically to the Agency information on all medicinal products for human use authorised or registered in the European Union by 2 July 2012, using this format. Furthermore, marketing authorisation holders have to inform the Agency of any new or varied marketing authorisations granted in the EU as of 2 July 2012, using this format.

Course Overview

The Agency has prepared this Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) 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).

Participants will be provided with explanations of the Extended EudraVigilance Product Report Message (XEVPRM) data elements and with various examples as to how to populate the XEVPRM taking into account different types of medicinal products authorised or registered in the EU. Participants will also have the opportunity to learn as to how to describe the characteristics of substances based on various substance classes such as chemicals, polymers, proteins, nucleic acids and structurally diverse materials (e.g. vaccines, advanced therapies) using practical examples. Participants that successfully pass the competency assessment following the course will receive a certificate.

Course Goals

At the end of this course, participants should be able to:

- Understand the concepts related to the electronic submission of information on medicines authorised or registered in the EU to the XEVMPD
- Describe the format and the data elements of the XEVPRM for authorised or registered medicinal products
- Describe the format and the data elements of the XEVPRM for substances of medicines
- Maintain the information on medicines in accordance with the legal requirements
- Discuss practical examples of medicinal products and substances

Course Audience

The XEVMPD training programme is targeting personnel of marketing authorisation holders, consultants and other organisations that are responsible for the electronic submission and maintenance of information on medicinal products authorised or registered in the EU.

[1] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000492.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac058033e8ad&jsenabled=true

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Extended EudraVigilance Medicinal Product Dictionary | Course Agenda

DAY ONE

08:45 – 09:15	**SESSION 1** Course Introduction Introduction to EudraVigilance EV Registration Process Regulatory Background (Legislation and legal notice)
09:15 - 10:30	**SESSION 2** Creation of an XEVPRM
10:30 - 10:50	COFFEE BREAK
10:50 - 12:30	**Session 2 (continued)** Creation of an XEVPRM Maintenance Operations Examples of medicinal products
12:30 - 13:30	LUNCH
13:30 - 15:30	**SESSION 3** Overview of the Structured Substance Information (SSI) Creation of SSI for Chemical Substance
15:30 - 15:50	COFFEE BREAK
15.50 - 17:30	**SESSION 3 (CONTINUED)** Creation of SSI for Proteins Creation of SSI for Nucleic Acids
17:45	END OF DAY ONE

DAY TWO

08:45 – 10:30	**SESSION 4** Creation of SSI for Polymer Substances Creation of SSI for Structurally Diverse Substances: - Vaccines - Herbals - Advanced therapies - Polyclonal immunoglobulins - Allergens Creation of SSI for Mixture Substances
10:30 - 10:50	COFFEE BREAK
10:50 – 12:30	**SESSION 5** Creation of SSI for Specified Substance Group 1 - Multiple substances - Herbal preparations Creation of SSI for Specified Substance Group 2 Creation of SSI for Specified Substance Group 3
12:30 – 13:30	LUNCH BREAK
13:30 – 15:30	**SESSION 6** Example of Substance Information in the XEVPRM Question and Answers
15:30 – 15:50	COFFEE BREAK
15:50 – 16:30	**SESSION 6** Competency Assessment Part 1: Multiple Choice Questions Part 2: Product Report Exam Case
16:45	END OF DAY TWO

Hotel and Travel Information

Recommended hotels nearby the EMA
Attendees must make their own hotel reservation
Ask for available EMA rate at:

Hilton London Docklands Riverside
265 Rotherhithe Street, London , SE16 5HW, UK
Telephone: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: reservations.docklands@hilton.com

Course Pre-requisites

Participants are expected to have basic background knowledge of:
EU legislation and the 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), second subparagraph of Regulation (EC) No. 726/2004
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&murl=menus/regulations/regulations.jsp&mid=WC0b01ac0580410138&jsenabled=true

To reach a wider audience, the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) training courses are offered face-to-face or through e-learning. The courses have been developed using a modular approach. Pharmaceutical companies intending to use the tools developed by the European Medicines Agency can additionally subscribe for a hands-on training module (face-to-face or e-learning) that facilitates the use of these tools for the electronic submission of medicines.

Details of the face-to-face training courses:

Duration:	2 days
Location:	European Medicines Agency (EMA) Canary Wharf, 7 Westferry Circus London E14 4HB, UK

REGISTRATION FORM

Extended EudraVigilance Medicinal Product Dictionary

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 OR EMAIL TO: PATRICK.BRUN@DIAEUROPE.ORG

Registrations will be accepted by fax or email. Each course is limited to 16 participants. The registration fee includes training course material, IT equipment and refreshments. The course may be cancelled if numbers of participants are not sufficient.

Standard fee	€ 1'050.00 ❑
Reduced Fee for Academia and Full Government	€ 525.00 ❑

SPECIAL DISCOUNT FOR SME (STATUS CONFIRMED BY EMA) AVAILABLE. MULTIPLE COURSE DISCOUNT AVAILABLE IF BOOKED TOGETHER WITH THE THREE DAY EUDRAVIGILANCE TRAINING COURSE. PLEASE CONTACT THE DIA FOR MORE INFORMATION.

NOTE: PAYMENT OF REGISTRATION FEES MUST BE RECEIVED BEFORE COMMENCEMENT OF THE COURSE

I wish to attend the following course:

(Please tick the date of the course you wish to attend)

1st	2nd choice		
❑	❑	27-28 October 2011	Course ID#11559
❑	❑	7-8 November 2011	Course ID#11592
❑	❑	17-18 November 2011	Course ID#11560
❑	❑	19-20 January 2012	Course ID#12502
❑	❑	24-25 January 2012	Course ID#12503

1st	2nd choice		
❑	❑	26-27 January 2012	Course ID#12504
❑	❑	9-10 February 2012	Course ID#12506
❑	❑	14-15 February 2012	Course ID#12507
❑	❑	16-17 February 2012	Course ID#12508
❑	❑	8-9 March 2012	Course ID#12510
❑	❑	20-21 March 2012	Course ID#12511
❑	❑	22-23 March 2012	Course ID#12512

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Street Address / P.O. Box

Postal Code City

Country Telephone

Fax (Required for confirmation)

Email (Required to receive presentation download instructions)

*For company billing, please add your company's VAT number:*_____

If you wish to be billed privately, please contact our Customer Services Team, as below

Please indicate your professional category: ❑ Academia ❑ Government ❑ Industry ❑ Contract Service Organisation

PAYMENT METHODS - Credit cards are the preferred payment method.

❑ Please charge my credit card - Credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

❑ VISA ❑MC ❑ AMEX

Card Number

Expiry Date

Cardholder's Name

Date Cardholder's Signature

❑ Cheques should be made payable to DIA and mailed together with a copy of the registration form for identification to: DIA Europe, Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ 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." including your name, company, Meeting ID# 11582 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.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00
Regretfully, if you do not cancel five working days prior to the course start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe 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 to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT: **Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.**

HOW TO REGISTER

The DIA Europe Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online www.diahome.org	**Fax** +41 61 225 51 52	**Email** diaeurope@diaeurope.org	**Mail** DIA Europe Postfach, 4002 Basel, Switzerland