

eXtended EudraVigilance Medicinal Product Dictionary Training Course

Two day training course including hands-on exercises



Key Topics

- General Terms and Definitions
- Registration in EudraVigilance and Qualified Person Responsible for Pharmacovigilance (QPPV) registration (incl. sponsor registration)
- XEVPRM XSD Schema
- XEVPRM data elements and examples including hands-on exercises
- Operation Types
- Data Quality
- Data Ownership
- XEVMPD technical validation rules
- Use of Controlled Vocabularies

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 in the EU
- Describe the format and the data elements of the XEVPRM for authorised medicinal products
- Discuss practical examples of different types of medicinal products
- Get hands-on experience in working with the XEVMPD
- Describe the format and the data elements of the XEVPRM for IMPs

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

The course is limited to 16 participants. Register early!

Training on electronic submission of information on medicines New pharmacovigilance legislation (Art. 57, paragraph 2, 2nd sub-paragraph, Regulation (EC) No. 726/2004)

Introduction

The European Medicines Agency (EMA) is implementing the electronic submission of information on medicines in the context of the new pharmacovigilance legislation (Art. 57, paragraph 2, 2nd sub-paragraph, Regulation (EC) No. 726/2004). On 05 March 2012, EMA published an updated set of mandatory requirements for marketing authorisation holders to comply with Article 57(2). The number of data fields initially required in the format published on 2 July 2011 was considerably reduced, thus significantly reducing the administrative burden and helping marketing authorisation holders to meet their legal deadline of 2 July 2012.

With regard to investigational medicinal products (IMPs), EMA is also facilitating the implementation of the provisions set out 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", chapter 7.9, paragraph 104).

Course Overview

The EMA 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).

The training focuses on explaining the guidance, 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 also known as EVWEB.

Participants who successfully pass the knowledge evaluation following the course will receive a notification from the European Medicines Agency that will allow them to register with EudraVigilance for the electronic submission of information on medicines in accordance with Article 57(2), second subparagraph of Regulation (EC) No. 726/2004.

The course also includes instructions for sponsors of clinical trials as how to provide information on the IMPs in the EudraVigilance Medicinal Product Dictionary ('EVMPD') before completing the clinical trials application form.

Course Audience

The XEVMPD training programme is targeting 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.

It is also targeting sponsors of clinical trials responsible for providing information on IMPs in accordance with the CT-3 detailed guideline.

The content of this training course is subject to regular updates in order to comply with new regulations and requirements.

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

EudraVigilance



What this course offers

- Training in meeting the requirements of the provisions of Article 57(2), second sub-paragraph of Regulation (EC) 726/2004 and the electronic submission of information on authorised medicinal products
- 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

Course Pre-requisites

Participants are expected to have basic background knowledge of:

- EU legislation and the revised 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) 726/2004
- 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”, chapter 7.9, paragraph 104).

Hotel and Travel Information

Attendees must make their own hotel reservation

Recommended hotel:

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

Web: <http://www.hilton.co.uk/docklands>

DIA was able to negotiate a special rate for participants to this training course. Room rate is GBP 145.00 (2012 rate) per room incl. breakfast excl. VAT.

To book a room, please consult the DIA web site.

DIA Upcoming Training Courses in Safety and Pharmacovigilance

EMA Excellence in Pharmacovigilance: Clinical trials and post-marketing
1-5 October 2012 | Vienna, Austria | ID 12566

How to Prepare for Pharmacovigilance Audits and Inspections
15-16 November 2012 | Prague, Czech Republic | ID 12575

Introduction to Signal Detection and Data Mining in Pharmacovigilance
14-15 November 2012 | Prague, Czech Republic | ID 12574

Medical Approach in Diagnosis and Management of ADRs
15-16 October 2012 | Paris, France | ID 12565

EudraVigilance Information Day at the European Medicines Agency
5 October 2012 | London, United Kingdom | ID 12534

IDMP Information Day at the European Medicines Agency
4 December 2012 | London, United Kingdom | ID 12536

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
16 October 2012 | London, United Kingdom | ID 12539
13 November 2012 | London, United Kingdom | ID 12540

EudraVigilance (EV) and eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

Course Agenda

DAY ONE

8:45 Session 1

Course Introduction
Introduction to EudraVigilance
Registration to EudraVigilance

Session 2

Regulatory Background
General Terms and Definitions
eXtended EudraVigilance Medicinal Product Report Message (XEVMPRM) Data Set
Operation Types
Data Quality
Data Ownership

Session 3

Database Architecture
Roles of the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) within EudraVigilance
Data Collection Process

COFFEE BREAK

Session 4

How to enter product data in the XEVMPD using the EVWEB tool
How to enter an organisation (MAH and Sponsor)
How to enter a substance (an approved and a development substance), translations and synonyms

LUNCH

Session 4 continued

Examples of different types of authorised medicinal products

- Nationally authorised medicinal product
- Medicinal product authorised through the mutual recognition procedure
- Centrally authorised medicinal product

Investigational Medicinal Product (Development Medicinal Product) for sponsors of clinical trials

17:45 END OF DAY ONE

DAY TWO

8:45 Session 5

How to perform simple and advanced queries in the XEVMPD using the EudraVigilance Web-based application (EVWEB)

Session 6

How to maintain product data in the XEVMPD using EVWEB
How to use the operation type “withdraw” for an authorised medicinal product

COFFEE BREAK

Example how to use the operation type “update” for substance (including the handling of translations and synonyms)
Example how to use the operation type “update” for an organisation

SANDWICH LUNCH

Knowledge Evaluation
Part 1: Multiple Choice Questions
Part 2: Product Report Exam Case

17:00 END OF DAY TWO

The Agenda is subject to change as course content is updated regularly in order to comply with new regulations and requirements.

REGISTRATION FORM

eXtended EudraVigilance Medicinal Product Dictionary Training Course



FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 OR EMAIL TO: GABRIELLA.SOKOLI@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

13-14 September 2012 ID12518

20-21 September 2012 ID12520

1st 2nd choice

01-02 October 2012 ID12522

25-26 October 2012 ID 12524

1st 2nd choice

26-27 November 2012 ID 12528

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, Kuechengasse 16, 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# 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
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