

# EudraVigilance Training on Electronic Reporting of ICSRs in the EEA

Course #15507

04-06 March 2015

Agencia Espanola Medicamentos y Productos Sanitarios (AEMPS), Spain

## OVERVIEW

EudraVigilance is the European data-processing network and management system, established at the European Medicines Agency (EMA) to support the electronic exchange, management and scientific evaluation of Individual Case Safety Reports (ICSRs) related to all medicinal products authorised in the European Economic Area (EEA).

This training course covers all aspects on the functionalities of the EudraVigilance system specifically EVWEB, with regard to electronic reporting of ICSRs including practical examples and exercises in the EudraVigilance training environment. It includes fundamentals of electronic transmission of ICSRs and ICH M2 safety and acknowledgment message specifications, as well as ICH E2B(R2) specifications on clinical safety data management in the frame of good pharmacovigilance practices and current EudraVigilance Business Rules. It should be noted that the course content is regularly updated in order to comply with new regulations and requirements.

Participants who pass the knowledge evaluation following this training course will receive a notification from the EMA that will allow them to register with the EudraVigilance production environment and to report ICSRs to the European Medicines Agency and/or the National Competent Authorities in the EEA. For more information on this registration process, please consult the EudraVigilance website.

## LEARNING OBJECTIVES

At the conclusion of this training course participants will be able to:

- Apply ICH rules to safety reporting
- Describe the Registration process with EudraVigilance
- Understand the concepts of electronic transmission of ICSRs
- Describe the EudraVigilance Gateway
- Describe the Webtrader functions
- Explain the reporting processes for fully-automated organisations, post-function users, and EVWEB users
- Create, validate and send safety messages (initial, follow-up reports, nullification reports, literature reports, parent-child, study reports, reports with medical and drug history)
- Create and send acknowledgments of received ICSR messages
- Query, view, browse and download safety reports
- Query, view and browse MedDRA through the EVWEB

## TARGET AUDIENCE

Professionals of Marketing Authorisation Holders, Sponsors of a Clinical Trials, National Competent Authorities or those acting on their behalf, in charge of pharmacovigilance and drug safety with legal reporting obligations in the EEA who wish to use the EudraVigilance system.

Participants are expected to have a minimal background knowledge of the EU Community legislation and guidance documents related to the monitoring of safety of clinical trials and post-authorisation pharmacovigilance activities that can be found on the EudraVigilance website:

<http://eudravigilance.ema.europa.eu/human/euPoliciesAndDocs.asp>



## DETAILS OF THE COURSE

Duration: 3 days

Location:

Agencia Espanola Medicamentos y Productos  
Sanitarios (AEMPS)  
Parque Empresarial Las Mercedes  
Edificio 8  
1 Campezo Street  
28022 Madrid  
Spain



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

**EudraVigilance**

**DIA** DEVELOP  
INNOVATE  
ADVANCE

EudraVigilance is regarded as one of the main pillars of the European Risk Management Strategy, which aims to strengthen the conduct of pharmacovigilance in the EEA.

Community legislation is in place to ensure that all stakeholders, including National Competent Authorities (NCAs), Marketing Authorisation Holders (MAHs) and sponsors of clinical trials in the EEA collect, collate and exchange adverse drug reactions. The electronic transmission of ICSRs, based on the results of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) remains a priority in the area of pharmacovigilance to make the adverse reaction data exchange and management more efficient.

EVWEB is an Internet-based reporting tool developed by the European Medicines Agency to allow Small and Medium Size Enterprises (SMEs) that hold marketing authorisations in the EEA and sponsors of clinical trials, to report electronically adverse reactions, in full compliance with the internationally agreed standards to the European Medicines Agency and NCAs.

The EudraVigilance Training Programme has been designed for:

- Organisations e.g. SMEs, (non-) commercial sponsors that intend to use EVWEB to implement electronic transmission of safety data. Organisations intending to use EVWEB are required to follow a training course to ensure the correct use of the reporting tool. They can apply for more than one person to be trained, or alternatively, send one person who will subsequently train other users internally in the organisation.
- Pharmaceutical companies that perform electronic transmission of ICSRs and use their locally established ICH compliant data-processing network (Gateway) and management system, may wish to attend this course to learn how to access and query the ICSRs that they have submitted to EudraVigilance.
- National Competent Authorities that wish to acquire knowledge about the functionalities of the tool, specifically in relation to data retrieval and evaluation to facilitate the scientific use of the data contained in the database.

### ***What this Training Course Is***

It is important that you have the proper expectations of what will be covered in this course.

This course is:

- Training on the EudraVigilance system, specifically the EVWEB
  - How the system relates to the ICH E2B(R2) guideline
  - How to navigate the system
  - How to enter information
  - Mandatory fields
- Training on the WEB Trader for transmission of files on the EudraVigilance Gateway
- Instruction on using EVWEB to browse MedDRA

### ***What this Training Course Is Not***

It is important that you have the proper expectations of what will not be covered in this course.

This course is not:

- Training on pharmacovigilance best practices
- Consulting on your organisation's business rules
- MedDRA training
- Training on data entry in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD)

## DAY ONE

### Module I: Fundamentals of Electronic Reporting of ICSRs

#### 09:00 Introduction

##### Session 1

- Concepts of Electronic Transmission of ICSRs
- Introduction to EudraVigilance
- Registration with EudraVigilance

##### Session 2

- Clinical Safety Data Management and Transmission of ICSRs - ICH E2B(R2)

#### 10:30 COFFEE BREAK

##### Session 3

- EudraVigilance Gateway and WEB Trader

##### Session 4

- ICSR Validation Business Rules

#### 12:30 LUNCH

### Module II: Creating and Validating ICSRs

#### 13:30 Session 5

- Creating a Safety Message

##### Session 6

- Saving and Printing Options

#### 15:30 COFFEE BREAK

##### Session 7

- Follow-up Report

##### Session 8

- Nullification Report

#### 18:00 END OF DAY 1

## DAY TWO

### Module II: Creating and Validating ICSRs (cont'd)

#### 09:00 Session 9

- Literature Report

##### Session 10

- Parent-child Report

##### Session 11

- Report with Medical and Drug History

#### 10:30 COFFEE BREAK

#### Session 12

- Study Report
- EudraVigilance Business Rules

#### 12:30 LUNCH

#### Session 13

- Receiving Acknowledgment Messages

#### Session 14

- Validation and Creating Acknowledgments

#### 15:30 COFFEE BREAK

#### Session 15

- WEB Trader - Post Function

#### Session 16

- What To Do in the Event of System Failure

#### 17:45 END OF DAY 2

## DAY THREE

### Module III: Query Functions, MedDRA in EudraVigilance

#### 09:00 Session 17

- MedDRA Simple and Advanced Queries

#### Session 18

- ICSR Simple and Advanced Queries

#### 10:30 COFFEE BREAK

#### Questions and review for Knowledge Evaluation

#### 12:30 LUNCH

### Module IV: Knowledge Evaluation

- Part 1: Multiple Choice Questions

- Part 2: ICSR Exam Case

#### Questions

#### 16:00 END OF DAY 3

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.

# REGISTRATION FORM

EudraVigilance Training on Electronic Reporting of ICSRs in the EEA # 15507  
04-06 March 2015, AEMPS, Madrid, Spain



## REGISTRATION FEES

Registration fee includes IT equipment, refreshment breaks, lunches and training course material.

FEES	
STANDARD	€ 1'745.00 □
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 865.00 □

**\*All fees will be subject to the Spanish VAT at 10%**

Please enter your Company's Spanish VAT number: \_\_\_\_\_

**Special discount - for SME (status confirmed by EMA) available. Please contact DIA for more information.**

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

The DIA Europe, Middle East and 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: [diaeurope@diaeurope.org](mailto:diaeurope@diaeurope.org) Mail: DIA Europe, Middle East and Africa,  
Küchengasse 16, 4051 Basel, Switzerland Web: [www.diahome.org](http://www.diahome.org)

## Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office four (4) 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
- Tutorial cancellation € 50.00

If you do not cancel four (4) weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

**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. Please notify the DIA office of such a substitution as soon as possible.

## Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

## 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

Fax Number

email (Required for confirmation)

## 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

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☐ **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 # 15507 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.diahome.org/EUTerms>

Date

Signature