The NEW EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: Hands-on Training Course

Date: 20-22 May 2019
Location: Lexington - AZCA, Madrid, Spain

OVERVIEW

EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines, which have been authorised in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network and launched a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in November 2017. The system makes use of the Individual Case Safety Report (ICSR) standards as developed by the International Organization for Standardization (ISO) in collaboration with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

This hands-on training course covers the functionalities of the new EudraVigilance web application (EVWEB). It includes practical examples for creating, sending and accessing ICSRs in the new ISO/ICH E2B(R3) format. It covers reporting principles in accordance with the guideline on good pharmacovigilance practices (GVP) Module VI "Management and reporting of adverse reactions to medicinal products" and explanations on how to comply with the EudraVigilance business rules and the EudraVigilance Access Policy.

The training course includes a knowledge evaluation for which participants, who pass the evaluation, will receive a notification from the EMA. Organisations, which aim to use EVWEB to start the electronic reporting of ICSRs to EudraVigilance for the first time, need to provide such notification for at least one user to be able to successfully register with the EudraVigilance production environment. For more information on the registration process, please consult the EMA website.

LEARNING OBJECTIVES

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

- Describe the EudraVigilance System components
- Apply ISO/ICH E2B(R3) rules to safety reporting based on practical examples for initial and follow-up reports, amendment and nullification reports, literature and parent-child cases, and reports from studies
- Understand how to use EVWEB to create, send and access ICSRs and acknowledgments
- Describe the principles of EVDAS and access by MAHs to use electronic Reaction Monitoring Reports (e-RMRs), line listings and ICSR forms
- Query, view, browse and download ICSRs using the EudraVigilance ICSR Download Functionality, which provides access by marketing authorisation holders (MAHs) to ICSRs submitted by national Competent Authorities (NCAs) in the EEA

TARGET AUDIENCE

Users of EudraVigilance – new users and users already trained on working with EudraVigilance including

- 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 obligations to report suspected adverse reactions related to medicines

BACKGROUND KNOWLEDGE

Participants are expected **to work in pharmacovigilance** and to have **basic background knowledge** of:

- The EU pharmacovigilance legislation
- GVP Module VI – Management and reporting of adverse reactions to medicinal products
- Guidance documents related to the monitoring of safety of clinical trials (CT3)
- GVP Module IX – Signal management and revised guidance on statistical methods

Further information on the new EudraVigilance system training can be found on the dedicated EMA EudraVigilance training page.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance

DIA

The updated European Union (EU) pharmacovigilance legislation brought about significant changes to electronic reporting requirements for suspected adverse reactions, to support better safety monitoring for medicines and a more efficient system for stakeholders. To support these changes, the EMA launched a new EudraVigilance system with enhanced functionalities in November 2017.

All stakeholders within the European Union (EU) medicines regulatory network are required to:

- implement simplified reporting procedure for ICSRs in the EU, with EMA receiving ICSRs from marketing authorisation holders and forwarding the reports to the national competent authorities concerned
- report non-serious cases of suspected adverse drug reactions that occur in the EEA to EudraVigilance
- use international data standards, including the ISO/ICH E2B(R3) data structure for individual case safety reports (ICSRs).

In addition, MAHs are required to monitor the EudraVigilance data they have access to for safety signals and to report these to EMA and national competent authorities in the EEA.

The main technical change to the EudraVigilance system are the implementation of the new ISO ICSR format for the submission and exchange of ICSRs in line with the applicable ICH E2B(R3) and EU ICSR Implementation Guides.

To incorporate the new format, EMA implemented several changes in EudraVigilance. These include:

- adapting the EudraVigilance Gateway, the secure electronic communication tool to exchange ICSRs, to accept ICH E2B(R2) as well as E2B(R3) files;
- adapting the EudraVigilance database management system (EDBMS) to support the storage and processing of reports submitted with the new ICH ICSR format;
- migrating all existing ICH E2B(R2) ICSR data to the new ICH ICSR format;
- redesign of EVWEB, the web application for the electronic reporting and management of ICSRs in the ISO ICSR format, using a new technology;
- introducing new functionalities in the EudraVigilance data analysis system (EVDAS), including the adrreports.eu portal, to support analysis of data and support signal management activities.

In addition, EMA added the following two new functionalities to the system:

- EudraVigilance rerouting functionality, which defines the rules for the forwarding of ICSRs to the NCA where the adverse reaction occurred (rules can be set by NCAs according to their needs and preferences);
- ICSR download functionality to enable MAHs to download ICSRs concerning their products or ICSRs reported with a substance for which they hold a marketing authorisation in the EEA.

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 version 8.0, specifically EVWEB
  - How the system relates to the ICH E2B(R3) guideline and the EU ICSR Implementation Guide
  - How to navigate the system
  - How to create ICSRs
  - Mandatory fields
- Training on the WEB-Trader for transmission of ICSRs on the EudraVigilance Gateway
- Instruction on using the ICSR download functionality for MAHs to access ICSRs in compliance with the EudraVigilance Access Policy

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 business processes
- Consulting on your organisation's business rules
- MedDRA training
- Training on data entry in the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)

DAY ONE

09:00   **Introduction**

09:30   **Session 1**
- Introduction to the New EudraVigilance System: components and functionalities
- Re-Routing of ICSRs to NCAs in the EEA
- ICSR download for MAHs

10:30   COFFEE BREAK

10:45   **Session 2**
Key elements of the new ICSR in ISO/ ICH E2B(R3) format

11.45   **Session 3**
EudraVigilance users and access rights

12:30   LUNCH

13:30   **Session 4**
Introduction to EVWEB Version 8.0

15:30   COFFEE BREAK

15:45   **Session 5**
- Creating an ICSR and sending of a safety message based on the following principles:
    - Initial report from the medical literature
    - Individual case refers to a parent-child report with medical and drug history for the parent and the child
- Saving and Printing Options

18:00   **END OF DAY 1**

DAY TWO

09:00   **START OF DAY 2**

Session 6
Creating an ICSR and sending of a safety message based on the following principles:
- Follow-up Report with a copy of the literature article that needs to be submitted as attachment
- Amendment report

10:30   COFFEE BREAK

Session 7
Creating an ICSR and sending of a safety message based on the following principles:
- Report from a non- interventional study

Session 8
Creating an ICSR and sending of a safety message based on the following principles:
- Report of a suspected unexpected serious adverse reaction (SUSAR) from an interventional clinical trial

12:30   LUNCH

13:30   **Session 9**
Creating an ICSR and sending of a safety message based on the following principles:
- Nullification of a case report

14:30   **Session 10**
Creating, sending and receiving acknowledgment messages

15.30   COFFEE BREAK

16:00   **Session 11**
Principles of obtaining access to EudraVigilance

17:30   **Questions and Answers**

18:00   **END OF DAY 2**

DAY THREE

09:00:   **START OF DAY 3**

Session 12
Access to EudraVigilance Data: EVDAS and EVWEB
- Electronic Reaction Monitoring Reports (e-RMRs) (explained)
- Line Listings of individual case safety reports (explained & demonstrated)
- ICSR forms (explained & demonstrated)

10:30   COFFEE BREAK

10:45   **Session 13**
- ICSR Simple and Advanced Queries
- EudraVigilance Export Manager: ICSR download functionality for MAHs

Session 14
- EV Post Function

Session 15
- What to do in case of failure

12:00   SANDWICH LUNCH

12:30   **KNOWLEDGE EVALUATION**
- Part 1: Multiple Choice Questions
- Part 2: Practical ICSR Exam Case

14.00   **END OF TRAINING COURSE**

REGISTRATION FORM

The NEW EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format
#19508 - 20-22 May 2019 - Lexington - AZCA, Madrid, Spain

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

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

FEES	
STANDARD	€ 1'850.00 ☐
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 925.00 ☐

Please enter your Company's Spanish VAT number: _____
"The reverse charge is applicable"

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.

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 CET. 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

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

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