

ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on Training Course using the EudraVigilance System

Duration: 3 days
Location: Lexington - AZCA, Madrid, Spain



OVERVIEW

The European Medicines Agency (EMA) launched the new EudraVigilance system in November 2017, which supports reporting and analysis of suspected adverse reactions originating from clinical trials and the post-authorisation phase of medicinal products using the **ICH E2B(R3) Individual Case Safety Report (ICSR) format**. The EMA operates the EudraVigilance system on behalf of the European Union (EU) medicines regulatory network.

This hands-on training course covers:

- In depth explanation and practical examples for creating, sending and accessing ICSRs in the ISO/ICH E2B(R3) format based on the EU ICSR Implementation Guide
- The use of the EudraVigilance web application (EVWEB) functionalities to describe the use of the E2B(R3) format and to practice examples for various reporting scenarios
- Reporting principles in accordance with the guideline on good pharmacovigilance practices (GVP) Module VI "Management and reporting of adverse reactions to medicinal products"
- How to comply with the EudraVigilance business rules and the EudraVigilance Access Policy
- Training on the transmission of ICSRs in the E2B(R3) format via the EudraVigilance Gateway (including WebTrader (EVWEB, EV Post and Gateway Traders)
- Instruction on using the ICSR download functionality for MAHs to access ICSRs

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:

- Apply the ISO/ICH E2B(R3) format and rules to safety reporting based on practical examples for initial spontaneous and follow-up reports, amendment and nullification reports, literature and parent-child cases, and reports from interventional and non-interventional studies
- Understand how to use EVWEB to create, send and access ICSRs and acknowledgments
- Describe the principles of the EudraVigilance Data Analysis System (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 from the EEA submitted by national Competent Authorities (NCAs) and MAHs

TARGET AUDIENCE

- Users who have to report and analyse suspected adverse reactions in the pre- and post-authorisation phase using the ISO/ICH E2B(R3) ICSR format
- Users of EudraVigilance – new users and users already trained on working with EudraVigilance
- Professionals of Marketing Authorisation Holders from all type of organisations performing electronic transmission of ICSRs, Gateway Traders and Web Trader (EVWEB and EV Post)
- Sponsors of 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

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

- The ICH pharmacovigilance guidelines
- 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.

LOCATION:

Lexington – Madrid - AZCA
Pº Castellana, 79
6th and 7th Floors
28046 Madrid
Spain

COURSE DATES:

09-11 October 2019



EUROPEAN MEDICINES AGENCY
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EudraVigilance

DIA

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 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).

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 signals to EMA and NCAs in the EEA.

The main technical change to the EudraVigilance system is 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(R3) as well as E2B(R2) files;
- Adapting the EudraVigilance database management system (EDBMS) to support the storage and processing of reports submitted in 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 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 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
- Changes in EudraVigilance registration process
- 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

Session 16

- EV query support options

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**