

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

Date: 26 - 28 October 2026 | Course ID - #26516

Location: Hotel Capital Plaza, Bucharest, Romania



OVERVIEW

EudraVigilance (EV) is the EU's system for managing and analysing information on adverse reactions to medicines which have been authorised or are being studied in clinical trials in the European Economic Area (EEA). The use of the ISO Individual Case Safety Report (ICSR) standard based on the ICH E2B (R3) modalities became mandatory on 30 June 2022.

For this training course, participants need to **bring their own device** and, prior to training, create an active EMA account to complete the exercises and post-course assessment in the EVWEB test environment (XCOMP).

Participants are also expected to work in pharmacovigilance or SUSAR submissions for clinical trials and to have basic background knowledge of:

- The ICH pharmacovigilance guidelines;
- The EU pharmacovigilance legislation;
- MedDRA coding;
- GVP Module VI – Management and reporting of adverse reactions to medicinal products;
- Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use;
- GVP Module IX – Signal management and revised guidance on statistical methods.

Following the completion of this course, participants who pass the knowledge evaluation will receive a notification from the EMA. Organisations which aim to register first user QPPV/RP or to use EudraVigilance web application (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 the EMA to be able to successfully register with the EV 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 Marketing Authorisation Holders (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.

Further information on the EudraVigilance system training can be found on the dedicated [EMA EudraVigilance training page](#).

COURSE DETAILS

DURATION: 3 DAYS

Timing

Days 1 & 2 - 09:00 - 18:00

Day 3 - 09:00 - 15:00

Venue

Hotel Capital Plaza,
Bd. Iancu de Hunedoara 54, sector 1,
011745 Bucharest, Romania

TARGET AUDIENCE

- Users who have to report and/or 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 performing electronic transmission of ICSRs, who operate as Gateway traders or as WebTrader (i.e., who use EVWEB or 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.

BENEFITS OF ATTENDING

- Have an in depth explanation of the EV system;
- Understand the principles for creating, sending and accessing ICSRs in EV based on the ISO/ICH E2B(R3) format;
- Comprehend the reporting principles of GVP Module VI;
- Practice various reporting scenarios using EVWEB and learn how to comply with the EV business rules;
- Train on the transmission of ICSRs via the EudraVigilance Gateway, including WebTrader (EVWEB and EV Post);
- Understand the principles of the EudraVigilance Access Policy and how to use the ICSR download functionality for MAHs to access ICSRs.

AGENDA

Timing in EET - Bucharest local time

DAY 1

- 09:00 **Introduction**
- 09:30 **Session 1**
Introduction to the enhanced EudraVigilance System:
- Components and functionalities
 - 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 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 2

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 3

09:00 **START OF DAY 3**

- Session 12**
- EV Post Function
- Session 13**
- What to do in case of failure
- Session 14**
- EV query support options

10:30 COFFEE BREAK

- 10:45 **Session 15**
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)
- Session 16**
- ICSR Simple and Advanced Queries
 - EudraVigilance Export Manager: ICSR download functionality for MAHs

12:00 SANDWICH LUNCH

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

15:00 **END OF TRAINING COURSE**

WHAT IS THIS TRAINING NOT

It is important to have the proper expectations of what will not be covered in this course. This course is not:

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

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