VIRTUAL EVENT

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

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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 an active EMA account for the practical exercises in the EVWEB test environment (XCOMP). Participants are required to have a good command of the English language and be proficient in using a computer and Zoom to participate effectively in the course.

Participants are also expected to work in pharmacovigilance/safety reporting (eg. SUSAR submissions for clinical trials) and to have basic background knowledge of:

- The ICH pharmacovigilance guidelines;
- The EU pharmaceutical legislation (Reg. 536/2014 and 726/2004, Dir. 2001/83/EC and CIR 520/2012);
- GVP Module VI – Management and reporting of adverse reactions to medicinal products (including GVP VI Addendum II);
- GVP Module IX – Signal management and revised guidance on statistical methods;
- MedDRA coding.

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 EV ICSR Download Functionality, which allows MAHs to access ICSRs from the EEA submitted by national Competent Authorities (NCAs) and other MAHs.

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

2027 COURSE DATES & TIME (CET/CEST)

- 01-05 February 2027 - 09:00 - 13:30, #27500
- 08-12 March 2027 - 14:00 - 18:30, #27501
- 12-16 April 2027 - 09:00 - 13:30, #27502
- 24-28 May 2027- 14:00 - 18:30, #27503
- 21-25 June 2027 - 09:00 - 13:30, #27504
- 20-24 September 2027 - 09:00 - 13:30, #27505
- 11-15 October 2027 - 14:00 - 18:30, #27506
- 08-12 November 2027 - 09:00 - 13:30, #27507
- 06-10 December 2027 - 14:00 - 18:30, #27508

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, on behalf of organisations that operate as Gateway partner 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 EV Gateway, including WebTrader (EVWEB and EV Post);
- Understand the principles of the EV Access Policy and how to use the ICSR download functionality for MAHs to access ICSRs.

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AGENDA (Timing in CET/CEST)

DAY 1 Module 1

09:00 or 14:00

Introduction

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

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

Session 3: EudraVigilance users and access rights

13:30 or 18:30 - End of Day 1

DAY 2 Module 2

09:00 or 14:00

Session 4: Introduction to EVWEB Version 8.0

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

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

13:30 or 18:30 - End of Day 2

DAY 3 Module 3

09:00 or 14:00

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

Session 9: Creating an ICSR and sending of a safety message based on the following principles:

- Nullification of a case report

13:30 or 18:30 - End of Day 3

DAY 4 Module 4

09:00 or 14:00

Session 10: Creating, sending and receiving acknowledgment messages

Session 11: Principles of obtaining access to EudraVigilance

Session 12: EV Post Function

Session 13: What to do in case of system failure

Session 14: EV query support options

13:30 or 18:30 - End of Day 4

DAY 5 Module 5

09:00 or 14:00

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

KNOWLEDGE EVALUATION

- Part 1: Multiple Choice Questions
- Part 2: Practical ICSR Exam Case

13:30 or 18:30 - End of Training

What this Training Course Is Not

To set clear expectations, this course is not:

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

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