



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



OVERVIEW

The European Medicines Agency (EMA) launched the enhanced 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. Based on a Pharmacovigilance Risk Assessment Committee (PRAC) recommendation, the EMA Management Board² confirmed and announced the mandatory use of the ISO Individual Case Safety Report (ICSR) standard based on the ICH E2B(R3)¹ modalities as of 30 June 2022 for all reporting to EudraVigilance. Furthermore, the ISO standard terminology for pharmaceutical forms and route of administration will also become mandatory at the same time. The use of the ICH E2B (R2) format will therefore be phased out.

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 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 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](#).

¹ <http://estri.ich.org/e2br3/index.htm>

² <https://www.ema.europa.eu/en/news/mandatory-use-international-standard-reporting-side-effects-improve-safety-medicines>

COURSE DATES AND TIME:

- Course #21500:
08 - 12 February 2021, 09:00 - 13:30 CET
- Course #21501:
08 - 12 March 2021, 14:00 - 18:30 CET
- Course #21502:
12 - 16 April 2021, 09:00 - 13:30 CEST
- Course #21503:
17 - 21 May 2021, 09:00 - 13:30 CEST
- Course #21504:
07 - 11 June 2021, 09:00 - 13:30 CEST
- Course #21505:
28 June - 02 July 2021, 14:00 - 18:30 CEST

BENEFITS OF ATTENDING:

- 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
- Various reporting scenarios using EVWEB
- Reporting principles in accordance with the guideline on GVP Module VI
- How to comply with the EudraVigilance business rules and the EudraVigilance Access Policy
- Training on the transmission of ICSRs via



EUROPEAN MEDICINES AGENCY
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DIA

Day 1 - Module 1

09:00 Or 14:00 CET

Introduction

Session 1

Introduction to the enhanced EudraVigilance System:

- Components and functionalities
- Changes in EudraVigilance registration process
- Re-Routing of ICSRs to NCAs in the EEA
- ICSR download for MAHs

Session 2

Key elements of the new ICSR in ISO/ ICH E2B(R3) format

Session 3

EudraVigilance users and access rights

13:30 or 18:30 CET

End of Day 1

Day 2 - Module 2

09:00 Or 14:00 CET

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 CET

End of Day 2

Day 3 - Module 3

09:00 Or 14:00 CET

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 CET

End of Day 3

Day 4 - Module 4

09:00 Or 14:00 CET

Session 10

Creating, sending and receiving acknowledgment messages

Session 11

Principles of obtaining access to EudraVigilance

Questions and Answers

Session 14

- EV Post Function

Session 15

- What to do in case of system failure

Session 16

- EV query support options

13:30 or 18:30 CET

End of Day 4

Day 5 - Module 5

09:00 Or 14:00 CET

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)

Session 13

- 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 CET

END OF TRAINING COURSE

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)

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