

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

**Duration:** 3 days

**Location:** Novotel, Bucharest, Romania



## 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 Board<sup>2</sup> confirmed and announced the mandatory use of the ISO Individual Case Safety Report (ICSR) standard based on the ICH E2B(R3)<sup>1</sup> 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](#).

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

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

## LOCATION:

Novotel Bucharest City Centre  
Calea Victoriei 37B Sector 1  
010061 Bucharest  
Romania

## COURSE DATES:

1-3 April 2020

## 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 the EudraVigilance Gateway, including WebTrader (EVWEB, EV Post and Gateway Traders)
- Instruction on using the ICSR download functionality for MAHs to access ICSRs



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

DIA

## DAY ONE

### 09:00 Introduction

#### 09:30 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

### 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 system 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

### *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)

# REGISTRATION FORM

ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on Training Course using the EudraVigilance System #20505 - 1-3 April 2020 - Novotel, Bucharest, Romania

EMAIL YOUR COMPLETED REGISTRATION FORM TO Business Travel.  
razvan.toma@businesstravel.ro or alexandru.popescu@businesstravel.ro

## REGISTRATION FEES

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

FEES	
STANDARD	€ 1'850.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 925.00 <input type="checkbox"/>

All fees as subject to the applicable Romanian VAT.

Please enter your Company's VAT number and Tax Office: \_\_\_\_\_

Special discount - for SME (status confirmed by EMA) on standard fee for a limited number of seats available. Please contact Business Travel for more information.

**Payment is due 7 days after registration and must be paid in full by commencement of the event.**

The Business Travel Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+4 021 231 56 15 Fax: +4 0372 203027

Email: razvan.toma@businesstravel.ro

Mail: Aleea Alexandru 9A, Bucharest, 011821, sector1, Romania

## Cancellation Policy

All cancellations must be made in writing and be received at the Business Travel Agency four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

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## Transfer Policy

You may transfer your registration - for the same course - to a colleague of the same organisation. Such a transfer is possible until 5 working days before the start of the training course. Please notify the Business Travel office of such a substitution as soon as possible.

## Event Stream and recording

We make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments.

## 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

Direct email attendee (Required for course material access)

## PAYMENT METHODS

**Credit cards:** Payments by VISA or Mastercard can be made by completing the details below. Please note that other types of credit card cannot be accepted.

**Please charge my**  VISA  MC

Card N°

Exp. Date  /

Cardholder's Name

**Bank transfers:** When Business Travel 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: Business Travel." 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 Business Travel.**

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