Virtual live hands-on training course for Clinical Trials Sponsors 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.

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 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.

Course Pre-requisites

Participants need an active EMA account for the practical exercises in the EVWEB test environment (XCOMP), 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 expected to work for a clinical trial sponsor organisation and to have basic background knowledge of Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use

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

Target Audience

This training course is intended for:

- ·Users who have to report and analyse SUSARs originated in the context of Clinical Trials, using the ISO/ICH E2B(R3) ICSR format
- ·Sponsors of Clinical Trials from Web Trader sender organisations (EVWEB and EV Post)

2026 Q1/Q2 COURSE DATES & TIME (CET)

- 10-12 February 2026, 09:00 - 13:00, # 26512
- 05-07 May 2026, 14:00 - 18:00, # 26513

LEARNING OBJECTIVES

At the end of this course you will be able to:
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- ·Apply the ISO/ICH E2B(R3) format and rules to safety reporting based on practical examples for cases (SUSARs) from interventional studies of clinical trials including initial reports as well as follow-up, amendment and nullification reports and parent-child cases.
- ·Understand how to use EVWEB to create, send and access ICSRs and acknowledgments.
- ·Query, view, browse and download ICSRs.

DIA

AGENDA (Timing in CE(S)T)

DAY 1 Module 1

09:00 or 14:00 - Start of Day 1

Introduction

Session 1: Introduction to the enhanced EudraVigilance System

- Components and Functionalities
- Registration with EudraVigilance
- Re-Routing of ICSRs to NCAs in the EEA

Session 2: Key Elements of the ICSR in ISO/ ICH E2B(R3) Format

11:00 or 15:30 Break

Session 3: EudraVigilance users and access rights

Session 4: Introduction to EVWEB Version 8.0

13:00 or 18:00 - End of Day 1

DAY 2 Module 2

09:00 or 14:00 - Start of Day 2

Session 5: Creating an ICSR and sending of a safety message based on a report of a suspected unexpected serious adverse reaction (SUSAR) from an interventional clinical trial [fatal case] */Theoretical part and practical exercise*

- Theoretical aspects of attachments, linked reports and parent child reports
- Follow-up Report
- Amendment Report with a copy of the laboratory results that needs to be submitted as an attachment
- Saving and Printing Options

11:00 or 15:30 Break

Session 6: Nullification of safety reports

Session 7: Receiving acknowledgment messages

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

DAY 3 Module 3

09:00 or 14:00 - Start of Day 3

Session 8: ICSR Simple and Advance Queries

Session 9: EV Post Function

Session 10: What to do in case of system failure

Session 11: EV query support options

11:00 or 15:30 Break

KNOWLEDGE EVALUATION

Part I – Multiple Choice Questions

Part II – Product Report Exam Case

13:30 or 18:30 - End of the course

What is NOT Covered In This Training Course

- Reporting of post-authorisation suspected adverse reactions (pharmacovigilance)
- Training on Clinical Trial Information System (CTIS)
- Training on pharmacovigilance business processes of your organisation
- Consulting on your organisation's business rules
- Training on MedDRA and XEVMPD - the Extended EudraVigilance Medicinal Product Dictionary