Virtual live hands-on training course for Clinical Trials Sponsors using the EudraVigilance system

| COURSE DATES AND TIME

Course # 23514
04-06 October 2023
09:00 – 13:00 CEST

Course # 23515
27-29 November 2023
14:00 – 18:00 CET

| COURSE PREREQUISITIES

Participants are expected to work for a clinical trial sponsor organisation and to have basic background knowledge of:

- Guidance documents related to the monitoring of safety of clinical trials (CT3)

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

| What will not be covered Training Course Is Not

- 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

| 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[1], the EMA Management Board confirmed and announced the mandatory use of the ISO Individual Case Safety Report (ICSR) standard based on the ICH E2B(R3)[2] modalities as of 30 June 2022 for all reporting to EudraVigilance. Furthermore, the use of ISO standard terminology for pharmaceutical forms and route of administration also became mandatory at the same time.

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

At the conclusion of this training course participants will be able to:

- 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

| 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)

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[1] https://www.ema.europa.eu/en/news/mandatory-use-international-standard-reporting-side-effects-improve-safety-medicines
[2] https://www.ich.org/page/e2br3-individual-case-safety-report-icsr-specification-and-related-files

AGENDA | TIMING IN CET/CEST

DAY 1

09:00	14:00	WELCOME AND 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	15:30	BREAK
		SESSION 3 – EudraVigilance users and access rights
		SESSION 4 - Introduction to EVWEB Version 8.0
13:00	18:00	END OF DAY 1

DAY 2

09:00	14:00	**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	15:30	BREAK
		SESSION 6 ▪ Nullification of safety reports **SESSION 7** ▪ Receiving acknowledgment messages
13:00	18:00	END OF DAY 2

DAY 3

09:00	14:00	**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	15:30	BREAK
		KNOWLEDGE EVALUATION ▪ Part I – Multiple Choice Questions ▪ Part II – Product Report Exam Case
13:00	18:00	END OF THIS TRAINING COURSE