

# Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Live Virtual Training Course for Sponsors of Clinical Trials using the EudraVigilance System

## | COURSE DATES AND TIME

### Course # 22513

02-04 February 2022  
09:00 – 13:00 CET

### Course # 22514

09-11 March 2022  
09:00 - 13:00 CEST

### Course # 22515

04-06 May 2022  
14:00 - 18:00 CEST

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

## | 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 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

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 initial SUSARs and follow-up reports, amendment and nullification reports, parent-child cases, and reports from interventional studies
- 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)



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



## AGENDA | TIMING IN CET/CEST

### DAY 1

09:00	13:00	<b>WELCOME AND INTRODUCTION</b>  <b>SESSION 1 - Introduction to the enhanced EudraVigilance System</b> <ul style="list-style-type: none"><li>▪ Components and Functionalities</li><li>▪ Re-Routing of ICSRs to NCAs in the EEA</li><li>▪ Registration with EudraVigilance</li></ul> <b>SESSION 2 - Key Elements of the ICSR in ISO/ ICH E2B(R3) Format</b>
11:00	15:30	<b>BREAK</b>  <b>SESSION 3 - EudraVigilance users and access rights</b>  <b>SESSION 4 - Introduction to EVWEB Version 8.0</b>
13:00	18:00	<b>END OF DAY 1</b>

### DAY 2

09:00	13:00	<b>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</b> <ul style="list-style-type: none"><li>▪ Theoretical aspects of attachments, linked reports and parent child reports</li><li>▪ Follow-up Report</li><li>▪ Amendment Report with a copy of the laboratory results that need to be submitted as attachment</li><li>▪ Saving and Printing Options</li></ul>
11:00	15:30	<b>BREAK</b>  <b>SESSION 6</b> <ul style="list-style-type: none"><li>▪ Nullification of safety reports</li></ul> <b>SESSION 7</b> <ul style="list-style-type: none"><li>▪ Receiving acknowledgment messages</li></ul>
13:00	18:00	<b>END OF DAY 2</b>

### DAY 3

09:00	13:00	<b>SESSION 8</b> <ul style="list-style-type: none"><li>▪ ICSR Simple and Advance Queries</li></ul> <b>SESSION 9</b> <ul style="list-style-type: none"><li>▪ EV Post Function</li></ul> <b>SESSION 10</b> <ul style="list-style-type: none"><li>▪ What to do in case of system failure</li></ul> <b>SESSION 11</b> <ul style="list-style-type: none"><li>▪ EV query support options</li></ul>
11:00	15:30	<b>BREAK</b>  <b>KNOWLEDGE EVALUATION</b> <ul style="list-style-type: none"><li>▪ Part I - Multiple Choice Questions</li><li>▪ Part II - Product Report Exam Case</li></ul>
13:00	18:00	<b>END OF THIS TRAINING COURSE</b>

# REGISTRATION FORM



## Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Live Virtual Training Course for Sponsors of Clinical Trials using the EudraVigilance System

You can register online at [www.diaglobal.org/EMA/course-listing](http://www.diaglobal.org/EMA/course-listing)

### REGISTRATION FEES

FEES	
STANDARD	€ 967.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 484.00 <input type="checkbox"/>

All registration fees are subject to VAT, if applicable.

Please enter your Company's European VAT number: \_\_\_\_\_

A special discount for SMEs on the standard fee is available for a limited number of places. To proof your status as an SME, a confirmation of the European Medicines Agency is necessary.

Please provide your SME number here : \_\_\_\_\_

**Payment is due 30 days after registration and must be paid in full by commencement of the course.**

Please select one course:

- Course # **22513**, 02-04 February 2022, 09:00 – 13:00 CET
- Course # **22514**, 09-11 March 2022, 09:00 - 13:00 CEST
- Course # **22515**, 04-06 May 2022, 14:00 - 18:00 CEST

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. :+41 61 225 51 51

**Email:** [Basel@DIAglobal.org](mailto:Basel@DIAglobal.org)

**Mail:** DIA Europe, Middle East & Africa, Kuchengasse 16, 4051 Basel, Switzerland

**Web:** [www.DIAglobal.org](http://www.DIAglobal.org)

### Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East and Africa office 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 28 days prior to the event start date and do not attend, you will be responsible for the full registration fee.

**Please note that switching from one course date to another is considered a cancellation and the same policy applies.**

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

### 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 DIA office of such a substitution as soon as possible.

### Event Stream and recording

If you attend a DIA event, 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. To view our full photography and video recording policy, click <https://www.diaglobal.org/general/photography-policy>.

### Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click <https://www.diaglobal.org/en/about-us/privacy-policy>.

### 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, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

- Please charge my  VISA  MC  AMEX

Card N°

Exp. Date  /

Cardholder's Name

- Bank transfers: When DIA 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: DIA." 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 DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on <http://www.diaglobal.org/EUTerms>

Date  Signature