EudraVigilance Training on Electronic Reporting of ICSRs in the EEA

Course # 17501
20-22 February 2017
Novotel Bucharest City Centre, Bucharest, Romania

OVERVIEW

EudraVigilance is the European data-processing network and management system, established at the European Medicines Agency (EMA) to support the electronic exchange, management and scientific evaluation of Individual Case Safety Reports (ICSRs) related to all medicinal products authorised in the European Economic Area (EEA).

This training course covers all aspects on the functionalities of the EudraVigilance system specifically EVWEB with regard to electronic reporting of ICSRs including practical examples and exercises in the EudraVigilance training environment. It includes fundamentals of electronic transmission of ICSRs and ICH M2 safety and acknowledgment message specifications as well as ICH E2B(R2) specifications on clinical safety data management in the frame of good pharmacovigilance practices and current EudraVigilance Business Rules. It should be noted that the course content is regularly updated in order to comply with new regulations and requirements.

Participants who pass the knowledge evaluation following this training course will receive a notification from the EMA that will allow them to register with the EudraVigilance production environment and to report ICSRs to the European Medicines Agency and/or the National Competent Authorities in the EEA. For more information on this registration process, please consult the EMA website.

LEARNING OBJECTIVES

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

• Apply ICH rules to safety reporting
• Describe the Registration process with EudraVigilance
• Understand the concepts of electronic transmission of ICSRs
• Describe the EudraVigilance Gateway
• Describe the Webtrader functions
• Explain the reporting processes for fully-automated organisations, post-function users, and EVWEB users
• Create, validate and send safety messages (initial, follow-up reports, nullification reports, literature reports, parent-child , study reports, reports with medical and drug history)
• Create and send acknowledgments of received ICSR messages
• Query, view, browse and download safety reports
• Query, view and browse MedDRA through the EVWEB

TARGET AUDIENCE

Professionals of Marketing Authorisation Holders, Sponsors of a Clinical Trials, National Competent Authorities or those acting on their behalf, in charge of pharmacovigilance and drug safety with legal reporting obligations in the EEA who wish to use the EudraVigilance system.

Participants are expected to have a minimal background knowledge of the EU Community legislation and guidance documents related to the monitoring of safety of clinical trials and post-authorisation pharmacovigilance activities that can be found on the EMA website:
EudraVigilance is regarded as one of the main pillars of the European Risk Management Strategy, which aims to strengthen the conduct of pharmacovigilance in the EEA.

Community legislation is in place to ensure that all stakeholders, including National Competent Authorities (NCAs), Marketing Authorisation Holders (MAHs) and sponsors of clinical trials in the EEA collect, collate and exchange adverse drug reactions. The electronic transmission of ICSRs, based on the results of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) remains a priority in the area of pharmacovigilance to make the adverse reaction data exchange and management more efficient.

EVWEB is an Internet-based reporting tool developed by the European Medicines Agency to allow Small and Medium Size Enterprises (SMEs) that hold marketing authorisations in the EEA and sponsors of clinical trials, to report electronically adverse reactions, in full compliance with the internationally agreed standards to the European Medicines Agency and NCAs.

The EudraVigilance Training Programme has been designed for:

• Organisations e.g. SMEs, (non-) commercial sponsors that intend to use EVWEB to implement electronic transmission of safety data. Organisations intending to use EVWEB are required to follow a training course to ensure the correct use of the reporting tool. They can apply for more than one person to be trained, or alternatively, send one person who will subsequently train other users internally in the organisation.

• Pharmaceutical companies that perform electronic transmission of ICSRs and use their locally established ICH compliant data-processing network (Gateway) and management system, may wish to attend this course to learn how to access and query the ICSRs that they have submitted to EudraVigilance.

• National Competent Authorities that wish to acquire knowledge about the functionalities of the tool, specifically in relation to data retrieval and evaluation to facilitate the scientific use of the data contained in the database.

What this Training Course Is
It is important that you have the proper expectations of what will be covered in this course.

This course is:

• Training on the EudraVigilance system, specifically the EVWEB
  • How the system relates to the ICH E2B(R2) guideline
  • How to navigate the system
  • How to enter information
  • Mandatory fields

• Training on the WEB Trader for transmission of files on the EudraVigilance Gateway

• Instruction on using EVWEB to browse MedDRA

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 the new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions

• Training on the ICH E2B(R3)/ISO ICSR standard

• Training on pharmacovigilance best practices

• Consulting on your organisation’s business rules

• MedDRA training

• Training on data entry in the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD)
## Day One
**Module I: Fundamentals of Electronic Reporting of ICSRs**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Topics</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Introduction</td>
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<tr>
<td></td>
<td>Session 1</td>
<td>- Concepts of Electronic Transmission of ICSRs</td>
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<tr>
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<td>- Introduction to EudraVigilance</td>
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<td>- Registration with EudraVigilance</td>
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<td>Session 2</td>
<td>- Clinical Safety Data Management and Transmission of ICSRs - ICH E2B(R2)</td>
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<td>10:30</td>
<td>COFFEE BREAK</td>
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<td>Session 3</td>
<td>- EudraVigilance Gateway and WEB Trader</td>
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<td>Session 4</td>
<td>- ICSR Validation Business Rules</td>
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<td>12:30</td>
<td>LUNCH</td>
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**Module II: Creating and Validating ICSRs**

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<th>Time</th>
<th>Session</th>
<th>Topics</th>
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<tbody>
<tr>
<td>13:30</td>
<td>Session 5</td>
<td>- Creating a Safety Message</td>
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<td>Session 6</td>
<td>- Saving and Printing Options</td>
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<td>15:30</td>
<td>COFFEE BREAK</td>
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<td>Session 7</td>
<td>- Follow-up Report</td>
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<td>Session 8</td>
<td>- Nullification Report</td>
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**Day Two**
**Module II: Creating and Validating ICSRs (cont’d)**

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<th>Time</th>
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<tbody>
<tr>
<td>09:00</td>
<td>Session 9</td>
<td>- Literature Report</td>
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<td>Session 10</td>
<td>- Parent-child Report</td>
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<td>Session 11</td>
<td>- Report with Medical and Drug History</td>
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**Day Three**
**Module III: Query Functions, MedDRA in EudraVigilance**

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<th>Time</th>
<th>Session</th>
<th>Topics</th>
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<tr>
<td>09:00</td>
<td>Session 17</td>
<td>- MedDRA Simple and Advanced Queries</td>
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<td></td>
<td>Session 18</td>
<td>- ICSR Simple and Advanced Queries</td>
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<td>10:30</td>
<td>COFFEE BREAK</td>
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<td></td>
<td>Session 19</td>
<td>- Questions and review for Knowledge Evaluation</td>
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<td>12:30</td>
<td>SANDWICH LUNCH</td>
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**Module IV: Knowledge Evaluation**

- Part 1: Multiple Choice Questions
- Part 2: ICSR Exam Case Questions

16:00 END OF DAY 3

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REGISTRATION FORM
EudraVigilance Training on Electronic Reporting of ICSRs in the EEA # 17501
20-22 February 2017, Novotel Bucharest City Centre, Romania

FAX OR EMAIL YOUR COMPLETED REGISTRATION FORM TO Business Travel Turism S.R.L.
Fax : +4 021 2315622, Email: madalina.nedelciu@businesstravel.ro

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

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<th>FEES</th>
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<td>STANDARD</td>
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<td>ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)</td>
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*Fees are subject to Romanian VAT at 9% and 19%.
Special discount - for SME (status confirmed by EMA) available.
Payment of registration fees must be received before commencement of the course.

ATTENDEE DETAILS:
Please complete in block capital letters or attach the attendee's business card here.

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First Name
Job Title
Company
Address
Postal Code
City
Country
Telephone Number
Fax Number

PAYMENT METHODS
After reception of your payment, Business Travel will send you a confirmation/invoice.

- Bank transfers:

  Participants from Romania will be charged in RON.
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  Romania
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  Mob.+4 0729 835 337

  Bank address: UNICREDIT TIRIAC BANK SA,
  Bd. Expozitiei Nr:1F, Sect 1, Bucharest, Cod Postal 012101, Romania
  Swift code: BACKROBU
  IBAN: RO84 BACX 0000 0010 6285 7002

  Payment should include your name, company and the remark „EudraVigilance” to ensure correct allocation of your payment.
  Payments must be net of all charges and bank charges must be borne by the payer.

- Credit Card

  If you wish to pay by credit card, please contact Business Travel.

Date  Signature