EudraVigilance Training on Electronic Reporting of ICSRs in the EEA

Course # 16512
23-25 May 2016
INFARMED, Lisbon, Portugal

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 EudraVigilance 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 EudraVigilance website: http://eudravigilance.ema.europa.eu/human/euPoliciesAndDocs.asp

DETAILS OF THE COURSE

Duration: 3 days
Location:
INFARMED
Parque de Saúde de Lisboa
Avenida do Brasil, 53
1749-004 Lisbon
Portugal

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance

DIA DEVELOP INNOVATE ADVANCE

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 Conference on Harmonisation of Technical Requirements for the Registration of 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 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

09:00   Introduction

Session 1
• Concepts of Electronic Transmission of ICSRs
• Introduction to EudraVigilance
• Registration with EudraVigilance

Session 2
• Clinical Safety Data Management and Transmission of ICSRs - ICH E2B(R2)

10:30   COFFEE BREAK

Session 3
• EudraVigilance Gateway and WEB Trader

Session 4
• ICSR Validation Business Rules

12:30   LUNCH

Module II: Creating and Validating ICSRs

13:30   Session 5
• Creating a Safety Message

Session 6
• Saving and Printing Options

15:30   COFFEE BREAK

Session 7
• Follow-up Report

Session 8
• Nullification Report

18:00   END OF DAY 1

DAY TWO
Module II: Creating and Validating ICSRs (cont'd)

09:00   Session 9
• Literature Report

Session 10
• Parent-child Report

Session 11
• Report with Medical and Drug History

10:30   COFFEE BREAK

Session 12
• Study Report
• EudraVigilance Business Rules

12:30   LUNCH

Session 13
• Receiving Acknowledgment Messages

Session 14
• Validation and Creating Acknowledgments

15:30   COFFEE BREAK

Session 15
• WEB Trader - Post Function

Session 16
• What To Do in the Event of System Failure

17:45   END OF DAY 2

DAY THREE
Module III: Query Functions, MedDRA in EudraVigilance

09:00   Session 17
• MedDRA Simple and Advanced Queries

Session 18
• ICSR Simple and Advanced Queries

10:30   COFFEE BREAK

Questions and review for Knowledge Evaluation

12:30   SANDWICH LUNCH

Module IV: Knowledge Evaluation

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

Questions

16:00   END OF DAY 3

REGISTRATION FORM

EudraVigilance Training on Electronic Reporting of ICSRs in the EEA
23-25 May 2016, INFARMED, Lisbon, Portugal
Please send this form to Geostar at Margarida.Benard@geostar.pt

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

FEES	
STANDARD	€ 1'745.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 865.00 ❑

Please enter your Company's Portuguese VAT number: _____

Special discount - for SME (status confirmed by EMA) on standard fee available. Please contact GeoStar for more information.

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

The GeoStar Team will be pleased to assist you with your registration from Monday to Friday between 09:30 and 18:30 CET.
Tel.: (+351) 21 3245244
Fax.: (+351) 21 3245241

Email: Margarida.Benard@geostar.pt
Mail:
GeoStar
onde a viagem começa
Praça dos Restauradores, nº 14
1250-187 Lisbon

Cancellation Policy
All cancellations must be made in writing and be received at the GeoStar 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.

GeoStar reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, GeoStar 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. Please notify the GeoStar office of such a substitution as soon as possible.

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   Fax Number
_____

email (Required for confirmation)

PAYMENT METHODS

For Portuguese Participants:

❑   Please contact GeoStar for the Refª MB
    Tel.: (+351) 21 3245244, email: Margarida.Benard@geostar.pt

For Participants from other European Countries:

❑   Bank transfers:

Please send your registration form together with the copy of the banktransfer to GeoStar. Payments should include your name, company and the remark "EudraVigilance" to ensure correct allocation of your payment. Please transfer to:

Banco Português de Investimento
Rua Tenente Valadim, 284
4100-476 Porto
Portugal
IBAN   PT50 0010 0000 7628 2730 0013 3
SWIFT/BIC BBPIPTPL

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 GeoStar.**

By signing below, I confirm that I agree with Geostar'sTerms and Conditions of booking as mentioned above.

Date	Signature