The course is limited to 16 participants. Register early.
## COURSE AGENDA

### DAY ONE

**Module I: Fundamentals of Electronic Reporting of ICSRs**

- **09:00** Introduction
- **09:30** Session 1
  - Concepts of Electronic Transmission of ICSRs
- **10:10** Session 2
  - Clinical Safety Data Management and Transmission of ICSRs - ICH E2B(M)
- **10:40** Questions
- **11:00** Coffee Break (included in the registration fee)
- **11:10** Session 3
  - EudraVigilance Gateway and WEB Trader
- **11:30** Session 4
  - ICSR Validation Business Rules
- **12:20** Questions
- **12:30** Lunch (not included in the registration fee)

**Module II: Creating and Validating ICSRs**

- **13:30** Session 5
  - Creating a Safety Message
- **15:30** Coffee break (included in the registration fee)
- **15:45** Session 6
  - Follow-up Report
- **16:15** Session 7
  - Nullification Report
- **16:45** Session 8
  - Literature Report
- **17:30** Questions
- **17:45** End of day 1

### DAY TWO

**Module II: Creating and Validating ICSRs (cont’d)**

- **09:00** Session 9
  - Parent-child Report
- **09:15** Hands-on Activity: Parent-child Report
- **09:45** Session 10
  - Report with Medical and Drug History
- **10:00** Session 11
  - Study Report
- **10:30** Session 12
  - Saving and Printing Options
- **11:00** Coffee break (included in the registration fee)

### DAY THREE

**Module IV: Query Functions, MedDRA in EudraVigilance**

- **09:00** Session 20
  - EVMPD Simple and Advanced Queries
- **09:30** Session 21
  - MedDRA Simple and Advanced Queries
- **10:00** Session 22
  - ICSR Simple and Advanced Queries
- **10:30** Questions and review for competency assessment
- **12:00** Coffee break (included in the registration fee)

**Module V: Competency Assessment**

- **13:00** Competency Assessment
  - Part 1: Multiple Choice Questions
  - Part 2: ICSR Exam Case
  - Part 3: Product Report Exam Case
- **15:00** Questions
- **16:00** End of day 3

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Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.

Speakers and agenda are subject to change without notice. Recording of any DIA tutorial/workshop information in any type of medium, is prohibited without prior written consent from DIA.
Learning Objectives

By the end of this training course, you should be able to do the Following within the context of EudraVigilance:

- Apply ICH rules to safety reporting
- Describe the EudraVigilance Gateway
- Describe the WEB Trader functions
- Explain the reporting processes for fully-automated organisations, Post-function users, and EVWEB users
- Create, validate and send safety messages
- Create, validate and send:
  - Follow-up reports
  - Nullification reports
  - Literature reports
  - Parent-child reports
  - Study reports
  - Reports with medical and drug history
- Create and send acknowledgments of received ICSR messages
- Query, view, browse and download safety reports
- Create, send and follow up on medicinal product reports
- Query, view, browse and download medicinal products in the EudraVigilance Medicinal Product Dictionary
- Query, view and browse MedDRA through the EVWEB

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(M) guideline
  - How to navigate the system
  - How to enter information
  - Mandatory fields
- Training on the WEB Trader for transmission of documents on the EudraVigilance Gateway
- Instruction on the EudraVigilance Medicinal Products Dictionary
- 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 practices
- Consulting on your company’s business rules
- MedDRA training

Hotel Information

Attendees must make their own reservation

Recommended hotels:

HOTEL HOLIDAY INN ****
10, Place de la République
75011 PARIS, FRANCE
Tel. +33 1 43 14 43 50

HOTEL LE QUARTIER***
39, Rue Jean Pierre Timbaud
75011 PARIS, FRANCE
Tel. +33 1 48 06 64 97

HOTEL HOME PLAZZA ****
74 Rue Amelot
75011 PARIS, FRANCE
Tel. +33 1 40 21 20 00

HOTEL BEL ORANGER***
30, Rue Lucien Sampaix
75010 PARIS, FRANCE
Tel. +33 1 42 08 19 74

GRAND HOTEL FRANÇAIS ***
223, Boulevard Voltaire
75011 PARIS, FRANCE
Tel. +33 1 43 71 27 57

HOTEL ECOLE CENTRALE***
3, Rue Bailly
75003 PARIS, FRANCE
Tel. +33 1 48 04 77 76
### Standard Fee:
- EUR **1'550.00**
- VAT 19.6%: EUR **303.80**
- Total Amount: EUR **1'853.80**

### Reduced Fee (Full Government/Full Academia):
- EUR **775.00**
- VAT 19.6%: EUR **151.90**
- Total Amount: EUR **926.90**

**Note:** Payment of registration fees must be received before commencement of the course

### CANCELLATION POLICY
Cancellations must be in writing and received at the DIA Europe office five working days prior to the course start. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Registrants who do not cancel within the five working days prior to the course start date and do not attend will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants are responsible for cancelling their own hotel and travel reservations.

### Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

### IMPORTANT:
Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.

### HOW TO REGISTER
The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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