Introduction to Pharmacovigilance

and Electronic Transmission of Individual Case Safety Reports (ICSR) for the use of Eudravigilance

A joint initiative of the European Medicines Agency with DIA acting as the conference organiser

Course dates

12 March 2013 | ID #13533
18 June 2013 | ID #13534
08 October 2013 | ID #13535
12 November 2013 | ID #13536

Details of the Course

Duration: 1 day

Location: European Medicines Agency
Canary Wharf
7 Westferry Circus,
London E14 4HB, UK

Capacity: Each course is limited to 16 participants

Course Overview

This one day course is designed for newcomers in pharmacovigilance, in particular individuals dedicated to data entry and quality review of ICSRs. The attendees will learn about the essentials of pharmacovigilance, the format, structure and content of ICSRs as well as data quality and coding principles, which are pre-requisites to comply with EU and international reporting requirements. This introductory course is strongly recommended to individuals that will be transmitting ICSRs to EudraVigilance.

Key Topics

- Legal/regulatory basis
- Compliance with reporting requirements for ICSRs
- What is a pharmacovigilance case: scope, criteria for validity
- Classification of cases: Solicited/ unsolicited, serious/not serious, etc
- Overview of the ICH E2B requirements
- Main differences of data elements and adverse reaction reporting during clinical trials and in the post-authorisation phase
- Overview of the case flow in the EU
- Concepts and data elements of an ICSR (the main part of the training, focusing on content and quality criteria of each important element)
- Case Follow-up: when and how it needs to be transmitted.
- Basic coding principles
- Data privacy requirements

Course Goals

At the conclusion of this course, participants should be able to:

- Understand the ICSR reporting requirements
- Understand the basic vocabulary of pharmacovigilance
- Complete properly the components of an ICSR
- Compare ICSR components for post-authorisation and clinical trials
- Identify the resources available for further guidance

Course Audience

This course is intended for newcomers in pharmacovigilance, who need to understand the basics of ICSRs with main focus on EU requirements.

EudraVigilance | EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH | DIA® www.diahome.org

COURSE AGENDA

09:00 COURSE INTRODUCTION

SESSION 1
PHARMACOVIGILANCE BACKGROUND AND REGULATORY FRAMEWORK

SESSION 2
KEY CONCEPTS AND DEFINITIONS

11:15 COFFEE BREAK

11:30 EXERCISES ON SESSION 2

SESSION 3
REPORTING REQUIREMENTS FOR EXPEDITED ICSR

13:00 LUNCH

14:00 EXERCISES ON SESSION 3

SESSION 4
REQUIREMENTS FOR DATA QUALITY IN ICSRS

15:45 COFFEE BREAK

16:00 SESSION 5
CODING, MEDDRA

SESSION 6
DATA PRIVACY PROTECTION

17:30 END OF DAY

Upcoming Courses in Safety and PharmacoVigilance

- **Benefit/Risk Management**
  13-14 May 2013 | Location to be confirmed | ID13523
  26-27 September 2013 | Prague, Czech Republic | ID 13524
- **Diagnosis and Management of Drug-Induced Liver injury (DILI)**
  September 2013 | Paris, France
- **How to Prepare for Pharmacovigilance Audits and Inspections**
  11-12 June 2013 | Location to be confirmed
- **Introduction to Signal Detection and Data Mining in Pharmacovigilance**
  10-11 June 2013 | Location to be confirmed
- **Pre-Marketing Clinical Safety**
  18-19 April 2013 | Vienna, Austria | ID 13526

European Medicines Agency Information Days and Courses

- **EudraVigilance Information Day**
  17 May 2013 | London, United Kingdom | ID 13529
  22 October 2013 | London, United Kingdom | ID 13530
- **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
  18-22 February 2013 | London, United Kingdom | ID 13502
  7-11 October 2013 | London, United Kingdom | ID 13522
- **IDMP International Standards ICH M5/M2 and the Implementation of eSubmission of MPIs in the EU, Article 57(2) Information Day**
  4 December 2012 | London, United Kingdom | ID 12536
  20 November 2013 | London, United Kingdom | ID 13531
- **The New Individual Case Safety Report (ICSR) International Standard and ICHE2B/M2 Information Day**
  05 February 2013 | London, United Kingdom | ID 13528
- **EudraVigilance courses:**
  EudraVigilance – Electronic reporting of ICSR
  eXtended EudraVigilance Medicinal Product Dictionary
  Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency

  Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
  For course details on EV, please click here.

Hotel and Travel Information

Recommended hotels nearby the EMA
Attendees must make their own hotel reservation
Ask for available EMA rate at:

Hilton London Docklands Riverside
265 Rotherhithe Street, London , SE16 5HW, UK
Telephone: +44 (0)20 7231 1001
Fax: +44 (0)20 7231 0599
Email: reservations.docklands@hilton.com

REGISTRATION FORM

Introduction to Pharmacovigilance and transmission of ICSR for the use of Eudravigilance
European Medicines Agency, London, UK

FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 or email to: Gabriella.Sokoli@diaeurope.org

FEES

Standard Fee	€ 600.00	❑
Reduced Fee for Academia/Government/ Non-profit (Full-Time)	€ 300.00	❑

Special discount - for SME (status confirmed by EMA) available. Multiple course discount available if booked together with the three day EudraVigilance training course.

The registration fee includes training course material, lunches and refreshments.

TOTAL AMOUNT DUE: _____

Each course is limited to 16 participants.
Courses may be cancelled if numbers of participants are not sufficient.
Payment of registration fees must be received before commencement of the course.

I wish to attend the following course in 2013:

1st	2nd choice		
❑	❑	12 March 2013	13533

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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, Event 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.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

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

If you do not cancel five working days prior to the event start date and do not attend, you 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 registered attendees. Registered attendees 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. Please notify the DIA Europe office of any such substitutions as soon as possible.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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