Introduction to Pharmacovigilance and Rules for Expedited Reporting of Individual Case Safety Reports (ICSRs) in Europe

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

Duration: 1 day

Location: European Medicines Agency (EMA)
30 Churchill Place
Canary Wharf
E14 5EU London, UK

OVERVIEW

This one day course covers the pre-requisites for the three day training course on EudraVigilance – electronic reporting of ICSRs and is therefore recommended to newcomers in pharmacovigilance, in particular individuals dedicated to data entry and expedited reporting. The attendees will learn about the essentials of pharmacovigilance, the format, structure and content of ICSRs as well as the rules for expedited reporting in Europe for both Clinical Trials and Post-Marketing ICSRs.

LEARNING OBJECTIVES

At the conclusion of this training course participants will 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

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

TARGET AUDIENCE

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

COURSE DATES:

6 October 2015 #15585

10 November 2015 #15586

DETAILS OF THE COURSE

Duration: 1 day
Location: European Medicines Agency (EMA)
30 Churchill Place, Canary Wharf
E14 5EU London, UK
Capacity: Each course is limited to 16 participants

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance

DIA DEVELOP INNOVATE ADVANCE

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 break

14:00 Exercises on session 3

Session 4
Requirements for data quality in ICSR

15:45 Coffee break

16:00 Session 5
Coding, MedDRA

Session 6
Data privacy protection

17:30 End of day

The Agenda is subject to change as course content is updated regularly in order to comply with new regulations and requirements

Hotel Information

Attendees have to make their own reservation.

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

Multiple Course discount

A multiple course discount is offered if booked together with the three day EudraVigilance training course that follows the Introductory course:

7-9 October 2015 #15502
11-13 November 2015 #15504

About DIA

In 1964, 30 visionary pharmaceutical research professionals came together with a noble mission – to increase communication and collaboration in drug development in order to improve safety and advance therapeutic success. Over the next 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.
DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: to improve health and well-being by transferring knowledge from those who have it to those who need it.
DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

REGISTRATION FORM

Introduction to Pharmacovigilance, European Medicines Agency (EMA), London, UK

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REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and training course material.

FEES	
STANDARD	€ 665.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/ NON-PROFIT (FULL-TIME)	€ 330.00 ❑

Special discount - for SME (status confirmed by EMA) available. Please contact DIA for more information.

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

I wish to attend the following course in 2015:

1st 2nd choice

❑ ❑ 6 October 2015 #15585

❑ ❑ 10 November 2015 #15586

The DIA Europe, Middle East and 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 Fax: +41 61 225 51 52 Email: emea@diaglobal.org Mail: DIA Europe, Middle East and Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.diahome.org/EudraVigilance for online registration.

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe, Middle East & 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.

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. Please notify the DIA office of such a substitution as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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

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.diahome.org/EUTerms

Date	Signature