European Medicines Agency Information Day:
The New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2 Information Day

Course #13528
5 February 2013
European Medicines Agency | London, United Kingdom

Programme Committee

Peter Arlett
Head of Sector Pharmacovigilance and Risk Management, European Medicines Agency (EMA), EU

Sabine Brosch
Business Lead, EudraVigilance and International Standardisation in Pharmacovigilance, European Medicines Agency (EMA), EU

Gaby Danan
Pharmacovigilance Expert, France

Anja van Haren
Medicines Evaluation Board (MEB), NL

Details of the Information Day

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

Capacity: The event is limited to 130 participants

Overview

In November 2012, step 4 of ICH E2B (R3) package has been signed off including the awaited implementation guide accompanied by several technical appendices. This step opens the way for the worldwide implementation of the new ICSR replacing progressively the current E2B (R2). This information day will present and explain the main and latest changes to E2B and its appendices as well as what, how and when they will be required in the EU and the US.

Key Topics

- Key differences between the ISO ICSR International Standard and the current ICH E2B(R2)guideline/M2 messaging format
- Initiation of pilot testing in collaboration between US FDA and EU
- ICH E2B(R3) Implementation Guide and consolidated comments from an EU and US perspective
- Health Level Seven (HL7) standard for electronic information exchange in the pharmaceutical and healthcare domain
- Use of MedDRA in the context of the new ICSR reporting – impact on coding and data retrieval

Learning Objectives

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

- Recognise the new requirements as regards the ICH E2B(R3) Implementation Guide and the ISO/HL7 messaging standards
- Update medicines regulatory authorities in the EU, pharmaceutical companies and IT vendors on the international standardisation work and the impact in the context of the new pharmacovigilance legislation
- Prepare for the implementation of the new ICSR standard and the adaptation of internal pharmacovigilance systems by all stakeholders involved (medicines regulatory authorities in the EU, IT vendors and pharmaceutical companies)
- Understand the use of MedDRA for reporting of medication errors, misuse, abuse and occupational exposure

Who Will Attend

- Representatives of IT departments of medicines regulatory authorities, pharmaceutical companies and service providers
- EU Qualified Persons Responsible for Pharmacovigilance (EU QPPVs)
- Pharmacovigilance staff of pharmaceutical companies and medicines regulatory authorities
- Pharmacovigilance software vendors
- Sponsors of Clinical Trials

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

DIA®
www.diahome.org

8:45 **Welcome and Opening Remarks**

Peter Arlett, EMA, EU

Session chairs:
Anja van Haren, MEB, NL and **Sabine Brosch**, EMA, EU

9:00 **Session 1**

HEALTH LEVEL 7: INDIVIDUAL CASE SAFETY REPORTS (ICSR) AND IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP) MESSAGING STANDARDS IN THE PHARMACEUTICAL AND HEALTHCARE DOMAIN

This Session will provide participants with an overview of the role of HL7 in the international standardization domain with main focus on the electronic exchange formats in the context of the new International Organzation for Standardizations (ISO) ICSR and IDMP standards. The impact on the pharmaceutical and healthcare domain and the expected benefits as regards interoperability and improved protection of public health will be presented on the basis of various use cases.

Speakers:
Mick Foy, MHRA, UK
Vada Perkins, FDA, US

09:45 **Session 2**

DIFFERENCES BETWEEN THE NEW ISO ICSR E2B(R3) STANDARD AND THE ICH ICSR E2B(R2) GUIDELINE CURRENTLY IN USE

This Session will provide the opportunity to obtain a clear understanding of the key differences between the new ISO ICSR standard and the current ICH E2B(R2) guideline/M2 message specifications for the electronic reporting of adverse reactions. The expected benefits and the impact on the pharmacovigilance business processes will be highlighted. Requirements for future pharmacovigilance system changes will be also addressed.

Speakers:
Gaby L. Danan, Pharmacovigilance Expert Consultant, France
Anja van Haren, MEB, NL

11:00 **Coffee Break**

11:30 **Session 3**

KEY COMMENTS FROM THE PUBLIC CONSULTATION ON THE ICH E2B(R3) IMPLEMENTATION GUIDE

This Session focuses on the summary of the main comments received in the EU and the US during the public consultation on the ICH E2B(R3) Implementation Guide. The comments disposition and resolution will be also addressed.

Speaker: **Sabine Brosch**, EMA, EU

USE OF MedDRA: FOCUS ON THE EXTENDED SCOPE OF ADVERSE REACTION REPORTING IN THE CONTEXT OF THE NEW PHARMACOVIGILANCE LEGISLATION

The collection of information on suspected adverse reactions will be addressed to include the use of medicinal products within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors and suspected adverse reactions associated with occupational exposure. The appropriate use of MedDRA to facilitate the ICSR coding and subsequent data analysis in these special situations will be also presented.

Speaker: **Patrick Revelle**, MedDRA MSSO
Discussant: **Victoria Newbould**, EMA, EU

12:30 **Lunch break**

13:30 **PM Session 4**

JOINT PILOT TESTING OF THE NEW ISO ICSR STANDARD IN THE EU AND THE US

This Session focuses on the preparation and outline of the conduct of a joint pilot testing of the new ICSR standard between FDA and the EudraVigilance Expert Working Group, which will be an important activity to prepare for a successful implementation of the ISO ICSR standard in the context of the new pharmacovigilance legislation.

Speakers:
Vada Perkins, FDA, US
Sabine Brosch, EMA, EU and Nick Halsey, EMA, EU
Discussant: **Victoria Newbould**, EMA, EU

14:00 **PM Session 5**

IMPLEMENTATION PLANNING OF THE NEW ICSR STANDARD

The aim of this Session is to discuss the preparation of an implementation strategy for the ICSR standard and the future ISO IDMP standard, both being strongly interlinked and taking into account the international dimension of pharmacovigilance.
Speaker from Pharmaceutical Industry invited

Speakers:
Vada Perkins, FDA, US
Sabine Brosch, EMA, EU
Alastair Fowkes, AstraZeneca, UK

15:00 **Coffee Break**

15:30 **Session 6**

This Session will provide participants with the opportunity to discuss practical implementation questions in the context of the management and reporting of adverse reactions to medicinal products. The ICSR data quality review process applied in EudraVigilance and related findings will be also highlighted.

QUESTION AND ANSWER SESSION ON GVP MODULE VI – MANAGEMENT AND REPORTING OF ADVERSE REACTIONS TO MEDICINAL PRODUCTS

Speaker: **Gilles Touraille**, EMA, EU

ICSR DATA QUALITY REVIEW IN EUDRAVIGILANCE

Speaker: **Nick Halsey**, EMA, EU

16:45 **End of Information Day**

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

HOTEL INFORMATION

Recommended Hotel:

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

DIA was able to negotiate a special rate for participants of the Information Day:
Room rate is GBP 145.00 per room incl. breakfast excl. VAT (rate of 2012)

To book a room, **click here.** Please fill in corporate account number: **481223696**.

The hotel is situated opposite of Canary Wharf conveniently connected by a shuttle boat. The landing stage is in walking distance to the European Medicines Agency (2 min). The ferry ticket is included in the room rate. Please make sure you receive it when checking in.

For further information, please go to http://www1.hilton.com/en_US/hi/hotel/LONNDHI-Hilton-London-Docklands-hotel/index.do

DIA 2013 Training Courses in Safety and Pharmacovigilance

- **Benefit/Risk Management**
  13-14 May 2013 | Germany | ID 13523
  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 | Amsterdam, Netherlands
  7–8 November 2013 | Paris, France
- **Introduction to Signal Detection and Data Mining in Pharmacovigilance**
  10-11 June 2013 | Amsterdam, Netherlands
  6–7 November 2013 | Paris, France
- **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**
  20 November 2013 | London, United Kingdom | ID 13531
- **The New Individual Case Safety Report (ICSR) International Standard and ICHE2B/M2 Information Day**
  5 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.

REGISTRATION FORM

European Medicines Agency Information Day
Course #13528 | 5 February 2013 | European Medicines Agency, London/UK

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

FEES

Standard Fee	€ 300.00	❑
Reduced Fee for Academia/Government/ Non-profit (Full-Time)	€ 150.00	❑

The registration fee includes training course material, sandwich lunch and refreshments.

TOTAL AMOUNT DUE: _____

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

❑ 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.

Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52 **Web** www.diaeurope.org **Mail** DIA Europe, Postfach, 4002 Basel, Switzerland