

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

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 Organization 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

Speaker from Pharmaceutical Industry invited

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.

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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

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September 2013 | Paris, France

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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

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For course details on EV, please [click here](#).



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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

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First Name

Company

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*(Required for confirmation)

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

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- 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.

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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.