European Medicines Agency Information Day: 2nd Information Day on the New Individual Case Safety Report (ICSR) International Standard and ICH E2B/M2

Course #11523
5 April 2011
European Medicines Agency | London, United Kingdom

Programme Committee

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

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Office of the Director, CBER, Food and Drug Administration, USA

Anja van Haren
EudraVigilance Coordinator, Medicines Evaluation Board, The Netherlands

Faculty

Paolo Alcini, Head of Section of Data Collection and Management, European Medicines Agency, EU

Nick Halsey
Scientific Administrator, European Medicines Agency, EU

Andrew Marr
Managing Director, Marr Consultancy Ltd, UK

Details of the Information Day

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

Capacity: The event is limited to 120 participants

Overview

The new ISO Individual Case Safety Report (ICSR) standard is being finalised in 2011. A major revision of the ICH E2B guideline is progressing based on the new ICSR standard with an ICH step 2 consultation of the ICH E2B(R3) Implementation Guide expected by the end of June 2011. The changes to the ICSR Final Draft International Standard (FDIS) will be presented and explained as well as the key aspects of the ICH ICSR Implementation Guide. Furthermore, expected changes to the ICSR reporting in the context of the new pharmacovigilance legislation will be discussed.

Key Topics

- Latest status of the ICH process and the international standards development
- Key differences between the ISO ICSR Draft International (DIS) and Final Draft International (FDIS) Standard
- ICH E2B(R3) Implementation Guide and regional requirements in the EU and the US
- Backwards and forwards compatibility between ICH E2B(R2) and ICH E2B(R3)
- Electronic reporting of ICSRs and EudraVigilance in the context of the new pharmacovigilance legislation
- Main principles of the ICSR Acknowledgement Message based on HL7 and ISO standards
- Planning for the implementation of the ISO Identification of Medicinal Products (IDMP) standard from an EU and US perspective

Learning Objectives

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

- Update medicines regulatory authorities in the EU, pharmaceutical companies and IT vendors on the ongoing international standardisation work
- Prepare medicines regulatory authorities in the EU, IT vendors and pharmaceutical companies for the implementation of the new ICSR standard and the adaptation of their pharmacovigilance systems
- Recognise the new requirements as regards the ICH E2B(R3) Implementation Guide and the ISO/HL7 messaging standards

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
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TUESDAY | 5 APRIL 2011

08:00 **REGISTRATION**

08:45 **Welcome**
Peter Arlett, European Medicines Agency, EU

Chairpersons for the whole day:
Sabine Brosch and Gaby Danan

09:00 **Session 1**

LATEST STATUS OF THE PROCESS AND THE INTERNATIONAL STANDARDS DEVELOPMENT

This session will provide participants with an update of the progress made in developing a new ICSR format by the International Conference on Harmonisation (ICH) and the Joint Initiative of the International Organisation for Standards (ISO), Health Level 7 (HL7) and the European Committee for Standardization (CEN). The objective is to improve the current ICSR and to achieve a wider interoperability of the information exchange across the regulatory and healthcare communities. The session will also provide an update on the strengthening of the collaboration with the ICH Global Cooperation Group (GCG) including non ICH countries with the goal to further strengthen harmonization beyond the current ICH regions.

Speaker: Andrew Marr

09:30 **Session 2**

KEY DIFFERENCES BETWEEN THE ISO ICSR DRAFT INTERNATIONAL AND FINAL DRAFT INTERNATIONAL STANDARD

This session aims to describe the key differences between the ISO ICSR Draft International Standard (DIS) and the Final Draft International Standard (FDIS). The ISO FDIS is the last step before an ISO standard is published, focusing on editorial improvements. The technical impact as regards the updated messaging format will be also addressed.

Speaker: Nick Halsey

10:15 **Session 3**

MAIN PRINCIPLES OF THE ICSR ACKNOWLEDGEMENT MESSAGE BASED ON HL7 AND ISO STANDARDS

The key principles of the ICSR acknowledgement messaging based on the HL7 and ISO standards will be explained in this session.

Speakers: Andrew Marr and Nick Halsey

10:45 **COFFEE BREAK**

11:15 **Session 3**

ICH E2B(R3) IMPLEMENTATION GUIDE AND REGIONAL REQUIREMENTS IN THE EU AND THE US

ICH has been working intensively in developing an ICH ICSR Implementation Guide, a new format which will address both user and technical guidance. In June 2011, ICH will aim to release the ICH ICSR Implementation Guide for a six months public consultation (ICH Step 2). This session will provide a detailed overview of the progress made in finalising this step 2 Implementation Guide and the key changes that are to be expected in comparison with the currently used ICH E2B(R2) guideline. The session will also highlight regional EU and US specific requirements that could not be accommodated in the ICH Implementation Guide. Opportunities and challenges as regards adverse reaction reporting requirements in the context of the new pharmacovigilance legislation will be also addressed.

Speakers: Anja van Haren, Gaby Danan and Vada Perkins

12:00 **SANDWICH LUNCH**

13:00 **Session 3 continued**

ICH E2B(R3) IMPLEMENTATION GUIDE AND REGIONAL REQUIREMENTS IN THE EU AND THE US

Speakers: Anja van Haren, Gaby Danan and Vada Perkins

14:00 **EUDRAVIGILANCE AND ELECTRONIC REPORTING OF ICSRS IN THE CONTEXT OF THE NEW PHARMACOVIGILANCE LEGISLATION**

This session will provide an overview of the preparation for the implementation of the new pharmacovigilance legislation in relation to the new adverse reaction reporting rules and EudraVigilance.

Speaker: Sabine Brosch
Discussant: Paolo Alcini

14:45 **COFFEE BREAK**

15:15 **Session 4**

ICH E2B(R2) AND (R3): HOW TO APPROACH THE BACKWARDS AND FORWARDS CONVERSION CONVENTIONS

This session will focus on the approach on how to ensure consistency in migrating from the current to the new ICSR standard. Backwards and forwards conversion conventions will be part of the ICH Implementation Guide, whereby the key principles and challenges will be highlighted during this session.

Speaker: Nick Halsey

16:00 **Session 5**

INTEGRATION OF THE ISO ICSR WITH THE ISO IDMP STANDARDS FROM AN EU AND US PERSPECTIVE

The aim of this session is to discuss the envisaged implementation approach for the new ISO ICSR and the future ISO IDMP standards from an EU and US perspective in the context of pharmacovigilance.

Speaker: Sabine Brosch and Vada Perkins

16:45 **END OF THE INFORMATION DAY**

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 (2010) is GBP 133.19 per room incl. breakfast excl. VAT

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 Upcoming Training Courses in Safety and Pharmacovigilance

Benefit/Risk Management
19-20 May 2011 | Prague, Czech Republic | ID 11562

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing
21-25 February 2011 | EMA, London, United Kingdom | ID 11549
3-7 October 2011 | Zagreb, Croatia | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections
10-11 May 2011 | Amsterdam, The Netherlands | ID 11542
November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance
9-10 May 2011 | Amsterdam, The Netherlands | ID 11543
November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs
19-20 September 2011 | Paris, France | ID 11530

Practical Guide for Pharmacovigilance: Clinical Trials and Post-Marketing
16-18 May 2011 | Nice, France | ID 11527

Pre-marketing Clinical Safety
4 April 2011 | Basel, Switzerland | ID 11565

DSURs Information Day at the European Medicines Agency
23 March 2011 | London, United Kingdom | ID 11579

EudraVigilance Information Day at the European Medicines Agency
10 May 2011 | London, United Kingdom | ID 11520
15 November 2011 | London, United Kingdom | ID 11522

IDMP Information Day at the European Medicines Agency
16 September 2011 | London, United Kingdom | ID 11524

ICSR Information Day at the European Medicines Agency
5 April 2011 | London, United Kingdom | ID 11523
16 November 2011 | London, United Kingdom | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency
17 November 2011 | London, United Kingdom | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of Eudravigilance at the European Medicines Agency
8 February 2011 | London, United Kingdom | ID 11550
7 June 2011 | London, United Kingdom | ID 11551
13 September 2011 | London, United Kingdom | ID 11552
6 December 2011 | London, United Kingdom | ID 11553

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)
Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.
For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

REGISTRATION FORM

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5 April 2011 | European Medicines Agency, London, United Kingdom

ID # 11523

DIA www.diahome.org

Registration includes participant material, coffee breaks and sandwich lunch. This event is limited to 120 participants.

Standard Fee	EUR 300.00 ❑
Reduced Fee for Academia and Full Government	EUR 150.00 ❑

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

TOTAL AMOUNT DUE: €_____ **NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT**

11523DIAWEB

RESPONSIBILITY/INTEREST AREA | Please select one Primary Interest Area (P) and one Secondary Interest Area (S) by placing a P or S on the appropriate line.

__ Advertising & Promotion
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__ Clinical Safety/Pharmacovigilance
__ Document Management/ eSubmissions
__ Manufacturing
__ Medical Communications
__ Medical Writing
__ Nonclinical
__ Outsourcing
__ Comparative Eff ectiveness/Health Technology Assessment/ Evidence-based Medicine
__ Pharmacology
__ Pricing/Reimbursement
__ Project Management
__ Professional Education, Training & Development
__ Public Policy/Law/ Corp. Compliance
__ Quality Assurance/Quality Control
__ Regulatory Aff airs
__ Research & Development
__ Statistics
__ Strategic Planning
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REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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PAYMENT METHODS - Credit cards are our preferred payment method.

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❑ 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." including your name, company, Meeting ID# 11523 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academia/Non-profit (Member/non-member) = € 100.00. Registered attendees who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registered attendees are responsible for cancelling their own hotel reservations. 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.

Transfer Policy
You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees 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.

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