

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

Course #10568

25 June 2010

European Medicines Agency, London, United Kingdom



## Programme Committee

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

**Gaby Danan**, Pharmacovigilance Expert, Global Pharmacovigilance and Pharmacoepidemiology, sanofi-aventis, France

**Andrew Marr**, Director, Global eRegulatory Development, Global Regulatory Operations, GlaxoSmithKline, United Kingdom

## Programme Faculty

**Nick Halsey**, Pharmacovigilance and Risk Management, European Medicines Agency (EMA), EU

**Raun Kupiec**, Senior Director Regulatory Affairs - Process Management, genzyme Europe, B.V., The Netherlands

**William Rosen**, Executive Director, Pharmacovigilance Information Management Standards & Policy, Pfizer Inc., USA

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

FDA speaker invited

## 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

## Course Overview

The European Medicines Agency is organising this public awareness event to update medicines regulatory authorities, pharmaceutical companies and IT vendors about the new international Individual Case Safety Report (ICSR) standard and the intended implementation at ICH level.

The ISO Draft International Standard (DIS) will be subject to balloting in May 2010 with a final International Standard (IS) expected by the end of 2010. In parallel, a release of the ICH ICSR Implementation Guide for Step 2 consultation is planned in the 2nd half of 2010. For the first time, the wider pharmacovigilance stakeholder community including IT vendors will have the opportunity to review and comment on the implementation of the new standard at ICH level.

EU and US experts, who have been strongly involved in the standards development and in the drafting of the ICH ICSR Implementation Guide will outline the technical and process related aspects that need to be taken into account in preparing for a coordinated, well-organised approach in putting the new standard in operation.

## Key Topics

- Background on the ICH process and the international standards development
- Key differences between the new ICSR ICH E2B(R3) and the current ICH E2B(R2) specifications
- Main principles of the new ISO ICSR and HL7 Acknowledgement Message standards
- Step 2 ICH E2B(R3) Implementation Guide and the backwards and forwards compatibility approach for the current and new standards
- Integration of the ISO Identification of Medicinal Products (IDMP) standard

## 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
- Recognise the main changes in comparison to the current ICH E2B(R2) guideline and ICH M2 message specifications
- 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

## 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

## NEED FOR THIS INFORMATION DAY

In May 2005, the revised ICH guideline for Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (ICSRs) (E2B(R3)) was released for public consultation. The ICH Steering Committee has taken a key decision that technical specifications should no longer be developed solely within ICH, but should be created in collaboration with Standards Development Organisations (SDOs) to enable wider inter-operability across the regulatory and healthcare communities. The ICSR is the first topic to go through this process.

The International Organisation for Standards (ISO), Health Level 7 (HL7) and the European Committee for Standardisation (CEN) have collaborated to form a Joint Initiative through which a single, common standard for the ICSR could be advanced. ICH representatives have been heavily involved in this initiative in addition to other experts from beyond the ICH community. The overall standard is based upon the HL7 ICSR model that is capable of supporting a wide range of product types (e.g. human medicinal products, veterinary products, medical devices etc.) The framework is described in:

- ISO/DIS 27953-1 Health informatics -- Pharmacovigilance - Individual case safety report -- Part 1: The framework for adverse event reporting  
The second part of the standard defined the details of the reporting requirements for human pharmaceuticals:
- ISO/ DIS 27953-2 Health informatics -- Pharmacovigilance - Individual case safety report -- Part 2: Human pharmaceutical reporting requirements for ICSR

It is envisaged that at some time in the future the standard would be extended by the addition of other Parts applicable to different product types.

ICH proposed to use this standard to meet the reporting requirements for E2B(R3). ICH will define the way that this standard should be used by the publication of an ICH Implementation Guide, which will define the use of the data elements as outlined in the E2B(R3) guideline. In addition, a harmonised approach to ensure backwards and forwards compatibility between the current ICH ICSR message specifications and the new standard – a major aspect during the transition phase until all stakeholders have upgraded their pharmacovigilance systems – will be addressed in the Implementation Guide.

FRIDAY | 25 JUNE 2010

**08:00 Registration**

**08:45 Welcome**

Peter Arlett, European Medicines Agency, EU

Chairpersons for the whole day:  
**Sabine Brosch and Andrew Marr**

**09:00 Session 1**

### ICH PROCESS AND COLLABORATION WITH STANDARDS DEVELOPMENT ORGANISATIONS

This session will provide participants with an understanding of the collaboration of the International Conference on Harmonisation (ICH) with Standards Development Organisations (SDOs). The aim is to enable wider inter-operability across the regulatory and healthcare communities. The ICSR is the first topic to go through this new standardisation process, whereby the International Organisation for Standards (ISO), Health Level 7 (HL7) and the European Committee for Standardization (CEN) agreed to form a Joint Initiative.

Andrew Marr, GlaxoSmithKline, UK

**09:45 Session 2 - Part I**

### DIFFERENCES BETWEEN THE NEW ISO ICSR E2B (R3) STANDARD AND THE CURRENT ICH ICSR E2B (R2) GUIDELINE

This session aims to describe the key differences between the new ISO ICSR standard and the ICH E2B(R2) guideline/M2 message specifications that currently serve as the basis for the mandatory electronic reporting of adverse reactions in the EU. The impact on the pharmacovigilance business processes will be also highlighted and requirements for future system changes.

Anja van Haren, Medicines Evaluation Board, NL  
Gaby Danan, sanofi-aventis, FR

**10:45 Coffee Break**

**11:15 Session 2 - Part II**

### DIFFERENCES BETWEEN THE NEW ISO ICSR E2B (R3) STANDARD AND THE CURRENT ICH ICSR E2B (R2) GUIDELINE

Anja van Haren, Medicines Evaluation Board, NL  
Gaby Danan, sanofi-aventis

**12:00 Sandwich Lunch**

## Hotel and Travel Information

Recommended hotels near the European Medicines Agency. Attendees must make their own hotel reservation. Ask for available European Medicines Agency rate at:

### Hilton London Docklands Riverside

265 Rotherhithe Street, London , SE16 5HW, UK  
Telephone: +44 20 7231 1001 - Fax: +44 20 7231 0599  
Email: [reservations.docklands@hilton.com](mailto:reservations.docklands@hilton.com)

### London Marriott Hotel West India Quay

22 Hertsmere Rd, Canary Wharf, London, E14 4ED, United Kingdom  
Phone: +44 20 70931000  
Fax : +44 20 70931001

**13:00 Session 3****OVERVIEW OF THE NEW ISO/HL7 ICSR AND ACKNOWLEDGEMENT MESSAGE STANDARDS**

The aim of this session is to provide an overview on how the new ISO/HL7 messages for ICSRs and acknowledgements are structured and organised. Concepts and messaging models will be also described.

FDA speaker invited  
Nick Halsey, European Medicines Agency, EU  
Raun Kupiec, Genzyme, NL

**14:00 Session 4****PART I  
ICH E2B (R3) IMPLEMENTATION GUIDE INCLUDING BACKWARDS AND FORWARDS COMPATIBILITY CONVENTIONS**

This session will focus on the description of the main chapters of the E2B(R3) Implementation Guide, which will describe on how the new ICSR standard will be implemented by ICH. In addition, the approach on how to ensure consistency in migrating from the current to the new ICSR standard by all stakeholders will be presented based on backwards and forwards compatibility conventions, which are also part of the ICH Implementation Guide.

William Rosen, Pfizer Inc., US  
Anja van Haren, Medicines Evaluation Board, NL

**15:00 Coffee break****15:30 Session 4 continued****PART II  
ICH E2B (R3) IMPLEMENTATION GUIDE INCLUDING BACKWARDS AND FORWARDS COMPATIBILITY CONVENTIONS**

William Rosen, Pfizer, US  
Anja van Haren, Medicines Evaluation Board, NL

**16:30 Session 5****PLANNING OF AN EU IMPLEMENTATION STRATEGY FOR THE NEW ICSR AND IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP) STANDARDS**

The aim of this session is to discuss the preparation of an EU Implementation Strategy for the new ICSR standard and the future IDMP standard, which are strongly interlinked for the purpose of pharmacovigilance. The timelines for the finalisation of the standards and the achievement of ICH step 4 of the Implementation Guide will be presented in the context of the overall planning.

Sabine Brosch, European Medicines Agency, EU

**17:00 End of Training Course****DIA UPCOMING TRAINING COURSES IN 2010****Clinical Research****Advanced GCP Study Monitoring**

4 June 2010 | Prague, Czech Republic | ID 10560  
19 November 2010 | Paris, France | ID 10561

**Clinical Project Management in Europe – Part I**

22-24 September 2010 | Basel, Switzerland | ID 10544

**Clinical Statistics for Non-Statisticians**

13-14 September 2010 | Paris, France | ID 10542

**Essentials of Clinical Study Management**

5-7 May 2010 | Vienna, Austria | ID 10527  
10-12 November 2010 | Lisbon, Portugal | ID 10528

**Practical GCP Compliance Auditing of Trials & Systems**

6-8 October 2010 | London, United Kingdom | ID 10546

**Regulatory Affairs****An Introduction to Product Information Management (PIM)**

26-27 April 2010 | Vienna, Austria | ID 10541  
28-29 October 2010 | Geneva, Switzerland | ID 10539

**Building the eCTD**

23-24 September 2010 | Basel, Switzerland | ID 10545

**Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview**

4-6 October 2010 | Location to be confirmed

**CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3**

26-28 April 2010 | Vienna, Austria | ID 10529  
5-7 December 2010 | United Arab Emirates | ID 10530

**European Regulatory Affairs: Review of Current Registration Procedures in the EU**

3-4 June 2010 | Prague, Czech Republic | ID 10538  
18-19 November 2010 | Paris, France | ID 10540

**Good Management of Medical Devices**

26-28 April 2010 | Paris, France | ID 10543  
27-29 October 2010 | Geneva, Switzerland | ID 10547

**US Regulatory Affairs**

18-21 October 2010 | Prague, Czech Republic | ID 10552

**Quality by Design**

Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

**Safety and Pharmacovigilance****Excellence in Pharmacovigilance: Clinical Trials and Post Marketing**

25-29 October 2010 | Vienna, Austria | ID 10533

**Introduction to Signal Detection and Data Mining in Pharmacovigilance**

26 April 2010 | Paris, France | ID 10550  
7 October 2010 | London, United Kingdom | ID 10558

**How to Prepare for Pharmacovigilance Audits and Inspections**

27 April 2010 | Paris, France | ID 10551  
8 October 2010 | London, United Kingdom | ID 10559

**Medical Approach in Diagnosis and Management of ADRs**

13-14 September 2010 | Paris, France | ID 10531

**Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing**

2-4 June 2010 | Prague, Czech Republic | ID 10525  
1-3 December 2010 | Paris, France | ID 10526

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

25 June 2010 | London, United Kingdom | ID 10568

**EudraVigilance Information Day at the European Medicines Agency**

22 June 2010 | London, United Kingdom | ID 10534  
19 October 2010 | London, United Kingdom | ID 10535

**EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)**

Courses throughout the year | European Medicines Agency, London, UK and selected European cities  
For course details on EV, please visit [www.diahome.org](http://www.diahome.org) > Training > EudraVigilance > Click on Related Courses

**Non-Clinical Sciences****Non-Clinical Safety Sciences and Their Regulatory Aspects**

22-26 November 2010 | Lisbon, Portugal | ID 10562

**All Curricular Areas****Crisis Management**

3-4 June 2010 | Basel, Switzerland | ID 10563  
14-15 October 2010 | Paris, France | ID 10564

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Speakers and agenda are subject to change without notice.  
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# REGISTRATION FORM

European Medicines Agency Information Day: The New Individual Case Safety Report (ICSR)

International Standard and ICH E2B/M2

25 June 2010 | European Medicines Agency, London, United Kingdom

ID# 10568



Registration includes participant material, coffee breaks and sandwich lunch. The 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**

**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.

10568DIAWEB

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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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☐ **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# 10568 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**

Cancellations received by this date are subject to an administrative fee of EUR 100.00.

Registrants who do not cancel five working days prior to the course start date and do not attend, 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 registrants. Registrants 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 but membership is not transferable. Substitute registrants 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.

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**Fax** +41 61 225 51 52

**Email** [diaeurope@diaeurope.org](mailto:diaeurope@diaeurope.org)

**Mail** DIA European Office  
Postfach, 4002 Basel, Switzerland