

ICH E2B (R3) Individual Case Safety Report (ICSR) Information Day

13 May 2014
Course #14502
European Medicines Agency (EMA), London, UK



Programme Committee

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Head Data Collection and Management, European Medicines Agency (EMA), EU

Peter Richard Arlett
Head of Pharmacovigilance, European Medicines Agency (EMA), EU

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Gaby Danan
Pharmacovigilance Expert, France

Anja van Haren
EudraVigilance Coordinator, Medicines Evaluation Board (MEB), The Netherlands

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

In November 2012, step 4 of the ICH E2B (R3) package has been signed off based on the ISO ICSR standard including the awaited implementation guide (IG) accompanied by several technical appendices. This step opened the way for the worldwide implementation of the ISO ICSR standard replacing progressively the current E2B (R2) version. The first package (version 1.01) was made available on 12 April 2013 to the users in order to begin the testing phase and the implementation of data exchange between partners.

In the context of the EU implementation, a regional IG is being prepared addressing EU specific requirements in relation to the application of the ISO ICSR standard and the E2B (R3) package.

This Information Day will address and explain the key changes expected in relation to the application of the new ISO ICSR standard and how those will impact the EU adverse reaction reporting and electronic transmission activities.

Key Topics

- Key differences between the ISO ICSR International Standard and the current ICH E2B(R2) guideline
- The ICH safety message flow in the EU
- Processing of safety and acknowledgement messages in case of technical or system failures
- EU specific business rules and technical ICSR validation
- Case classification
- ICSR specific concepts and their application in the EU (e.g. amendment report, causality assessment)
- Coding of medicinal product information
- Use of MedDRA in the context of the new ICSR reporting
- Handling of attachments
- EMA testing procedures with stakeholders

Learning Objectives

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

- Recognise the new requirements as regards the ICH E2B (R3) and EU region specific implementation
- 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 the new ICSR format in line with EU pharmacovigilance legislation

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 Richard Arlett, EMA, EU

Session chairs:

Anja van Haren, MEB, NL and Sabine Brosch, EMA, EU

9:00 Session 1**KEY DIFFERENCES BETWEEN THE NEW E2B (R3) ICSR AND THE ICH ICSR E2B (R2)**

This session will provide a summary of the differences between the new ICH E2B (R3) and the current E2B (R2) ICSR format in the context of the electronic reporting of adverse reactions in the EU. The expected benefits and the impact on the pharmacovigilance business processes will be highlighted.

Speakers:

Anja van Haren, MEB, NL

Gaby L. Danan, Pharmacovigilance Expert, France

Discussant: Diane Farkas, Sanofi-Aventis, France

10:00 Session 2**ELECTRONIC ICSR REPORTING PROCESS**

This session will describe the procedures concerning the Electronic Data Interchange (EDI) of ICSRs and the roles of all involved stakeholders taking into account the simplification of adverse reaction reporting as foreseen in Article 107(3) of Directive 2001/83/EC and Article 28(1) of Regulation (EC) 726/2004.

The ICSR safety message flow in the EU

Nick Halsey, EMA, EU

10:45 Coffee Break**11:15 Session 3****EU SPECIFIC BUSINESS RULES AND TECHNICAL ICSR VALIDATION**

Key changes to the business rules as currently applied in EudraVigilance will be presented. These changes are based on the new ISO ICSR standard, the ICH E2B (R3) Implementation Guide and taking into account EU specific requirements and processes.

EU specific business rules and case classification

Nick Halsey, EMA, EU and Edurne Lazaro, AEMPS, ES

12:30 Sandwich lunch**13:30 Session 4****ICSR SPECIFIC CONCEPTS AND THEIR APPLICATION IN THE EU**

This session will address the handling of amendment reports, attachments and principles of causality of assessment. Principles of handling medicinal product information will be also elaborated.

Concepts of the new ICSR applied in the EU

Anja van Haren, MEB, NL

Discussants: Sabine Brosch, EMA, EU and Victoria Newbould, EMA, EU

Handling of medicinal product information in ICSRs

Tom Paternoster-Howe, EMA, EU and Ilaria Del Seppia, EMA, EU

Discussant: Ana Silvia Cochino, EMA, EU

15:00 Coffee Break**15:30 Session 5****EMA TESTING PROCEDURES AND INDUSTRY PERSPECTIVES**

The Preparation for the new ICSR implementation from a pharmaceutical industry perspective

Diane Farkas, Sanofi-Aventis, France

An outline of potential testing procedures for the new E2B (R3) ICSR format

Tom Paternoster-Howe, 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.

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HOTEL INFORMATION

Recommended Hotel:

Hilton London Docklands Riverside

265 Rotherhithe Street, London, SE16 5HW, UK

Telephone: +44 20 7231 1001

Email: reservations.docklands@hilton.com

DIA has blocked a limited number of rooms at the rate of GBP 139.00 single and GBP 149.00 double room/night including breakfast and VAT. To make your booking please visit the DIA event website.

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

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13 May 2014 | London, United Kingdom | ID 14502
 - **EnCePP Information Day**
Dates to be confirmed | London, United Kingdom | ID 14503
 - **Excellence in Pharmacovigilance: Clinical trials and post-marketing**
13-17 October 2014 | London, United Kingdom | ID 14548
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November 2014 | London, United Kingdom | ID 14549
- EudraVigilance courses:
- EudraVigilance – Electronic reporting of ICSRs in the EEA
 - eXtended EudraVigilance Medicinal Product Dictionary
 - Introduction to Pharmacovigilance and Rules for Expedited Reporting of Individual Case Safety Reports (ICSRs) in Europe

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For information on EudraVigilance courses, please visit www.diahome.org > Meetings & Training > About Meetings & Training > In-Person Instruction > EudraVigilance > EudraVigilance Courses

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6th ICH E2B (R3) Individual Case Safety Report (ICSR) Information Day
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FAX YOUR COMPLETED REGISTRATION FORM TO: +41 61 225 51 52 or email to: diaeurope@diaeurope.org

FEES

Standard Fee	€	365.00	<input type="checkbox"/>
Reduced Fee for Academia/Government/ Non-profit (Full-Time)	€	150.00	<input type="checkbox"/>

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.

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PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

Prof Dr Ms Mr

Last Name

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

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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.**

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- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
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