6th ICH E2B (R3) Individual Case Safety Report (ICSR) Information Day

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

Programme Committee

Sabine Brosch
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EudraVigilance Coordinator, Medicines Evaluation Board (MEB), The Netherlands

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

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

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TUESDAY, 13 MAY 2014

Information Day chairs:
Sabine Brosch, EMA, EU and Anja van Haren, MEB, NL

08:45-09:00 WELCOME AND OPENING REMARKS
Peter Richard Arlett, EMA, EU

09:00-10:00 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, Case management and Medical Evaluation Head, Sanofi-Aventis, France

10:00-10:45 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

10:45-11:15 COFFEE BREAK

11:15-12:30 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

12:30-13:30 SANDWICH LUNCH

13:30-15:00 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
Ana Silvia Cochino, EMA, EU and Ilaria Del Seppia, EMA, EU

15:00-15:30 COFFEE BREAK

15:30-16:45 Session 5
EMA TESTING PROCEDURES AND INDUSTRY PERSPECTIVES

Preparation for the new ICSR implementation from a pharmaceutical industry perspective
Diane Farkas, Case management and Medical Evaluation Head, 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

REGISTRATION FORM

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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
Reduced Fee for Academia/Government/ Non-profit (Full-Time)	€	180.00

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.

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

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*(Required for confirmation)

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- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 100.00.

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