Individual Case Safety Report (ICSR) Information Day

29 April 2015
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

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

Sabine Brosch
Principal Scientific Administrator, Monitoring and Incident Management, Pharmacovigilance, European Medicines Agency (EMA), EU

Gaby Danan
Pharmacovigilance Expert, France

Nick Halsey
Scientific Administrator, European Medicines Agency (EMA), EU

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

ADJACENT EVENT

28 April 2015

Information Day on New Services and Systems in Pharmacovigilance: Preparing for Business Change

European Medicines Agency

DETAILS OF THE INFORMATION DAY

Location
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Capacity: The event is limited to 110 participants

NEED FOR THIS ICSR INFORMATION DAY

The finalisation of the ISO ICSR standard and the associated ICH E2B(R3) Implementation guide has opened the way for the worldwide implementation of the ISO ICSR standard and for it to progressively replacing the current E2B (R2) specification.

Following the completion of the ICH E2B(R3) implementation guide, the European Implementation Guide (IG) for the ISO ICSR standard was published in January 2015. The EU IG addresses 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 this will impact the EU adverse reaction reporting and electronic transmission activities.

KEY TOPICS

- Implementation of the new ISO ICSR standard and the impact on pharmacovigilance activities
- Planning of activities in the EU – what needs to be done and when
- Key aspects of the new EU ICSR Implementation Guide
- How to prepare for the testing with the new ISO ICSR standards
- Latest developments of the ISO IDMP standards and the interplay with ISO ICSR
- Latest developments in MedDRA
- Q&As developed by the ICH E2B Implementation Working Group

TARGET AUDIENCE

- Qualified Persons Responsible for Pharmacovigilance (QPPVs)
- Individuals involved in pharmacovigilance, safety database and information management
- IT system developers and data managers

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1995 2015 EMA

DIA DEVELOP INNOVATE ADVANCE

08:30 **REGISTRATION**

08:45 **WELCOME NOTE**

Peter Richard Arlett, EMA

09:00 **SESSION 1**

THE NEW ISO ICSR FORMAT - IMPLEMENTATION PLANNING AND KEY CHANGES IMPACTING PHARMACOVIGILANCE

The aim of this session is to discuss the preparation of an implementation strategy for the ISO ICSR standard, both being strongly interlinked and taking into account the international dimension of pharmacovigilance.

This session will also 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. Requirements for future pharmacovigilance system changes will be also addressed.

Session co-chairs: Sabine Brosch, EMA, and Anja van Haren, MEB

ICSR (R3) implementation planning and move to simplified adverse reaction reporting in the EU
Nick Halsey, EMA

Key changes from E2B(R2) to E2B(R3) and the impact on your pharmacovigilance activities
Anja van Haren, MEB and Gaby Danan, PhV expert

ICSR (R3) implementation planning in the US and Japan
Alastair Fowkes, AstraZeneca, member of the EV-EWB and ICH E2B IWG

10:30 **COFFEE BREAK**

11:00 **SESSION 2**

HOW TO APPROACH THE ISO/ICH (R3) ICSR IMPLEMENTATION?

This session will focus on the approach as to how to ensure consistency in migrating from the current to the new ICSR standard and the new testing procedure that will be put in place. In addition, backwards and forwards conversion conventions will be part of the EU and ICH Implementation Guides, for which the key principles and challenges will be highlighted during this session.

Co-chairs: Anja van Haren, MEB, and Nick Halsey, EMA

The new EU ICSR Implementation Guide - what you need to know
Nick Halsey, EMA

How to manage transition: an approach to backwards/&forwards conversion between E2B(R2) and E2B(R3)
Fatima Sadurdine Hergy, INFARMED

Changes to the processes for ICSR (R3) testing
Tom Paternoster-Howe, EMA
Discussant: Alastair Fowkes, AstraZeneca, member of the EV-EWB

12:30 **SANDWICH LUNCH**

13:30 **SESSION 3**

ISO IDMP LATEST DEVELOPMENTS AND INTERPLAY WITH ISO ICSR

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.

Co-chairs Paolo Alcini, EMA, and Sabine Brosch, EMA

ISO IDMP - the latest developments
Vada Perkins, CBER, FDA

Interplay of the ISO ICSR and ISO IDMP standards
Nick Halsey

Master Data Management (MDM) roadmap
Kepa Amutxastegi, EMA

ISO IDMP Implementation: Current status in EU
Ilaria Del Seppia, EMA

Discussants: Paolo Alcini, EMA
Ilaria Del Seppia, EMA
Alastair Fowkes, AstraZeneca, member of the EV-EWB and ICH E2B IWG

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

HOT TOPICS IN ADVERSE REACTION REPORTING

This session will focus on upcoming changes relating to MedDRA through the addition of a new SOC and look at the working being done on a mobile application facilitate ADR reporting. In addition the latest updates from the ICH E2B(R3) implementation working group will be discussed.

Co-chairs: Anja van Haren, MEB, and Sabine Brosch, EMA

27th MedDRA SOC and impact on your pharmacvigilance systems
Judy Harrison, MedDRA MSSO

ICH E2B(R3) Implementation Working Group - Questions & Answers

IMI-WEB-RADR - mobile app for ADR reporting and the future ISO ICSR standards

17:00 **END OF THE INFORMATION DAY**

HOTEL INFORMATION

Recommended Hotel:

Hilton London Docklands Riverside
265 Rotherhithe Street
London, SE16 5HW
United Kingdom
Telephone: +44 20 7231 1001
Email: reservations.docklands@hilton.com

DIA has blocked a limited number of rooms at the rate of GBP 179.00 single and GBP 191.00 double room/night (Tuesday to Thursday) including breakfast and VAT. To make your booking please use the reservation link available on 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 (10 min). The ferry ticket is included in the room rate. Please make sure you receive it when checking in.

REGISTRATION FORM

Individual Case Safety Report (ICSR) Information Day
29 April 2015 European Medicines Agency, London, United Kingdom

ID #15221

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: diaeurope@diaeurope.org Fax: +41 61 225 51 52 For more information please call +41 61 225 51 51

Registration fees*	Fees
Industry	400.00 EUR ❑
Government/Academia/Charitable/Non-Profit (full time)	200.00 EUR ❑

*Registration fee includes: refreshments, sandwich lunch and delegate material

Payment is due 30 days after registration and must be paid in full by commencement of the event.

ATTENDEE DETAILS

Please complete in block capital letters or attach the attendee's business card here.

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

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

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **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." Please include your name, company, Event ID #15521 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. **If you have not received your confirmation within five working days, please contact DIA Europe.**

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking. These are available from the office or on http://www.diahome.org/EUTerms

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

- Industry (Member/Non-member) € 200.00
- Government/Academia/Charitable/Non-Profit (full time) € 100.00

If you do not cancel four weeks 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 or postponed, 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.

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.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.
Email diaeurope@diaeurope.org **Tel.** +41 61 225 51 51 **Fax** +41 61 225 51 52
Web www.diaeurope.org **Mail** DIA Europe, Middle East & Africa Contact Centre Team, Küchengasse 16, 4051 Basel, Switzerland