Individual Case Safety Report (ICSR) Information Day

26 April 2016
European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

Peter Richard Arlett
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Member of the EV-EWG and ICH E2B IWG

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Member of the EV-EWG

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EMA, EU

Francisco Penaranda Fernandez
Head, Business Data and Analytics Department, EMA, EU

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Pharmacovigilance and Risk Management, EMA, EU

Patrick Revelle
Director, MedDRA MSSO, US

Gilles Touraille
Pharmacovigilance and Risk Management, EMA, EU

OVERVIEW

The 2010 European Union (EU) Pharmacovigilance legislation foresees further enhancements to EudraVigilance, particularly to support the collection, management and analysis of suspected adverse reaction reports. This includes the implementation and use of the new ISO Individual Case Safety Report (ICSR)/ICH E2B(R3) standard which delivers on better data structures, data quality as well as interoperability with healthcare systems. This is an important element to contribute to the promotion and protection of public health through the optimisation of the safe and effective use of medicines.

This information day is aimed at providing pharmacovigilance experts of medicines regulatory authorities and marketing authorisation holders with an update on the latest developments as regards the implementation of the new ICSR format as part of the enhanced EudraVigilance functionalities, the revision of the Guideline on Good Pharmacovigilance Practices (GVP) Module VI – Management and reporting of adverse reactions to medicinal products as well as plans for the future integration with the ISO Identification of Medicinal Products (IDMP) standards. Aspects of external stakeholder testing and the Agency's approach to provide large scale user training will be also addressed. Feedback on the Agency's workshop with IT vendors as well as the use of the MedDRA 27 System Organ Class (SOC) "Product issues" will be also provided. Key aspects as part of the implementation planning will be also addressed.

KEY TOPICS

- Adverse Reaction Reporting and Analysis, EudraVigilance: System Changes to Come
- EudraVigilance change management planning, external stakeholder testing and training programme
- Implementation of the new ISO/ICH E2B(R3) ICSR standard and the impact on pharmacovigilance
- Data coding and analysis using MedDRA 27th SOC "Product issues"
- Latest developments of the ISO IDMP standards and the interplay with ISO ICSR
- ISO/E2B(R3) ICSR implementation planning in the EU and beyond

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

DIA DEVELOP INNOVATE ADVANCE

08:30 REGISTRATION

08:45 WELCOME NOTE

Peter Richard Arlett, EMA

09:00 SESSION 1

ADVERSE REACTION REPORTING AND ANALYSIS, EUDRAVIGILANCE: SYSTEM CHANGES TO COME

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

Taking into account the requirements set out in pharmacovigilance legislation, this session will focus on providing an overview of the EudraVigilance system enhancements, which are subject to an independent audit in 2016. It will also give an insight into the planning of the external testing and the Agency's large scale training approach for stakeholders.

EudraVigilance – summary of key functionalities to be audited and the impact on stakeholders
Francois Domergue, EMA

Access to EudraVigilance by Marketing Authorisation Holders: How will it work?
Francois Domergue, EMA

EudraVigilance training curriculum for stakeholders
Francois Domergue, EMA

Discussants: Margaret Walters, member of the EV-EWG, MSD, Augusto Filipe, Tecnimede, member of the EV-EWG, Pedro Oliveira, EMA, and Rodrigo Postigo, EMA

10:30 COFFEE BREAK

11:00 SESSION 2

IMPLEMENTATION OF THE NEW ISO/ICH E2B(R3) ICSR STANDARD, MEDDRA AND THE IMPACT ON PHARMACOVIGILANCE

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

This session will provide an overview of the key changes anticipated as part of the revision of GVP Module VI in the context of the transition to the ISO/ICH E2B(R3) ICSR. A summary of key changes to the EudraVigilance business rules that will be applied as part of the new ICSR validation will also be provided. The session will conclude with a presentation on the use of the new 27th MedDRA SOC in the context of product issues including operational examples.

The ISO/ICH E2B(R3) ICSR – what will change in GVP module VI?
Gilles Touraille, EMA

The ISO/ICH E2B(R3) ICSR – what will change as part of the EudraVigilance business rules?
Anja van Haren, MEB, and Nick Halsey, EMA

Update on new MedDRA SOC Product issues: industry and regulatory perspectives
Judy Harrison, MedDRA MSSO

Utility of SOC 27 – operational examples
David Lewis, member of the EV-EWG, Novartis

Discussants: Patrick Revelle, MedDRA MSSO, Gaby Danan, PhV expert, Neil Newman, member of the EU ISO IDMP Task Force, Eli Lilly, and Augusto Filipe, Tecnimede, member of the EV-EWG

12:30 SANDWICH LUNCH

13:30 SESSION 3

ISO/ICH E2B(R3) ICSR IMPLEMENTATION PLANNING

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

The session will highlight important business process changes from an MAH perspective, address the ISO/ICH E2B(R3) ICSR implementation planning and will provide a summary of the ICSR workshop organised by the Agency in March with IT vendors in support of the ISO ICSR standards implementation.

How to prepare for the business process change?
Alastair Fowkes, AstraZeneca, member of the EV-EWG and ICH E2B IWG

ICSR implementation planning beyond the EU – how should industry prepare?
David Lewis, Novartis

Feedback on the Agency's ICSR workshop with IT vendors
Nick Halsey, EMA

Discussants: Gaby Danan, PhV expert, Margaret Walters, member of the EV-EWG, MSD, and Neil Newman, member of the EU ISO IDMP Task Force, Eli Lilly

15:00 COFFEE BREAK

15:30 SESSION 4

ISO IDMP LATEST DEVELOPMENTS AND INTERPLAY WITH ISO ICSR

Session co-chairs: Francisco Penaranda Fernandez, EMA, and Nick Halsey, EMA

The aim of this session is to update on the ISO IDMP standardisation activities and the impact on the ISO/ICH E2B(R3) implementation.

ISO IDMP and pharmacovigilance – session introduction
Sabine Brosch, EMA

The implementation of ISO IDMP for identification of medicinal products
Francisco Penaranda Fernandez, EMA

The implementation of the ISO IDMP standards from an industry perspective
Neil Newman, member of the EU ISO IDMP Task Force, Eli Lilly

Discussants: Alastair Fowkes, member of the EV-EWG and ICH E2B IWG, AstraZeneca, Anja van Haren, MEB, and David Lewis, member of the EV-EWG, Novartis

17:00 END OF THE INFORMATION DAY

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

REGISTRATION FORM

Individual Case Safety Report (ICSR) Information Day
26 April 2016 European Medicines Agency, London, United Kingdom

ID #16521

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM, E-mail: EMEA@DIAglobal.org
Fax: +41 61 225 51 52. You can also register online: www.diaglobal.org/ICSRinfoday . 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

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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." Please include your name, company, Event ID #16521 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 EMEA.**

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

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA EMEA 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) (Member/Non-member) € 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 EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA EMEA 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 EMEA 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 EMEA 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.
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