

European Medicines Agency: 3rd Information Day

New Identification of Medicinal Products (IDMP) International Standards, ICH M5/M2 and the Implementation of Electronic Submission of Medicinal Product Information in the EU (Article 57(2) Requirements of the New Pharmacovigilance Legislation)

Course #12536

4 December 2012

European Medicines Agency, London, UK



Programme Committee

Peter Arlett, Head of Sector Pharmacovigilance and Risk Management, European Medicines Agency (EMA), EU

Sabine Brosch, Business Lead, EudraVigilance and International Standardisation in Pharmacovigilance, European Medicines Agency (EMA), EU

Gaby Danan, Pharmacovigilance Expert, France

Vada Perkins, U.S. Food and Drug Administration (FDA), CBER, US

Key Note Speaker

Rostislava Dimitrova, Policy Officer, Risk Assessment, DG SANCO European Commission (EU)

Programme Faculty

- Paolo Alcini, Head of Section Data Collection and Management (DCM), EMA, EU
- John Kiser, Senior Director, Regulatory Operations, Abbott, US
- Raun Kupiec, Senior Director, Regulatory Affairs Europe, Process Management Group, Genzyme Europe, NL
- Ilaria Del Seppia, Scientific Administrator, DCM, EMA, EU
- Panagiotis Telonis, Scientific Administrator, DCM, EMA, EU

Learning Objectives

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

- Understand the ongoing international standardisation work on IDMP
- Understand the e-health network activities and the ongoing work towards addressing interoperability challenges related to medicines
- Recognise the main new features of the future IDMP messaging specifications
- Prepare medicines regulatory authorities in the EU, IT vendors and pharmaceutical companies for the implementation of the new IDMP standards and adaptation of their regulatory product management and Pharmacovigilance systems
- Understand the maintenance requirements for the electronic submission of medicinal product information by marketing authorisation holders, in compliance with the Article 57(2) provisions of Regulation (EC) 726/2004.

Course Overview

The five new International Identification of Medicinal Product (IDMP) standards are expected to be finalised and published by the International Organization for Standardization (ISO) by the end of 2012. Implementation of these standards in the area of pharmacovigilance is further defined in the Commission Implementing Regulation (EU) 520/2012. The IDMP standards were developed in response to a worldwide demand for internationally harmonised specifications for exchanging medicinal product information in a robust and reliable manner. IDMP is one of a group of five standards, which together provide the basis for the unique identification of medicinal products.

The IDMP standards support the regulation of medicines and pharmacovigilance including Individual Case Safety Reports (ICSR). IDMP supports the activities of medicines regulatory agencies worldwide by jurisdiction.

Furthermore, under eHealth Governance Initiative (eHGI) semantic and technical interoperability has been identified as a key priority for modern healthcare delivery.

In the context of the international harmonisation activities, ICH is aiming to reach step 2 for public consultation of the M5 IDMP Implementation Guide (IG) in the next months. As per agreement with the ICH Steering Committee, the electronic submission of information on medicinal products and substances will be based on the Health Level 7 (HL7) Structured Product Labeling (SPL) IDMP messaging format, a major step forward in the international harmonization activities.

The course will provide important news on the eHealth Network activities and the challenges in semantic and technical interoperability of information on medicinal products. Data elements and message specifications as well as definitions of concepts for key terminologies in accordance with the ICH M5 IG will be further explained. The use of HL7 SPL IDMP Common Message Element Types (CMETs) will also be outlined in detail.

Furthermore, the Information Day will provide a forum to update stakeholders on the implementation activities in the context of the new pharmacovigilance legislation, more specifically, Article 57(2), second subparagraph of Regulation (EC) 726/2004. This will also include new aspects on maintenance of information on medicinal products.

Key Topics

- e-health and interoperability challenges related to medicinal products
- Key principles of the ICH M5 IDMP Implementation Guide
- Use of HL7 SPL IDMP CMETs for the electronic exchange of information on medicinal products and substances
- Article 57(2) and maintenance of information on medicinal products by marketing authorization holders
- Questions and Answers on Article 57(2) implementation
- Industry perspective on Article 57(2) and ISO IDMP standards implementation

Who Will Attend

- Regulatory affairs staff of pharmaceutical companies
- 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
- Medicinal product management software vendors
- Sponsors of clinical trials



TUESDAY – 04 DECEMBER 2012

Chairs of this Information Day:

Sabine Brosch, EMA, EU and **Vada Perkins**, FDA, US

08:15 REGISTRATION

08:45 WELCOME NOTE

09:00 **KEYNOTE: THE ACTIVITIES OF THE E-HEALTH NETWORK AND INITIATIVES IN ADDRESSING TECHNICAL AND SEMANTIC INTEROPERABILITY RELATED TO MEDICINES**

Speaker: **Rostislava Dimitrova**, Policy Officer, Risk Assessment, DG SANCO European Commission, EU

9:45 **Session 1**

THE NEED FOR STANDARDISATION IN THE PHARMACEUTICAL DOMAIN

This session will provide an introduction to the standardisation work in the pharmaceutical domain in the context of the new EU pharmacovigilance legislation and US FDA's labeling requirements.

Electronic submission of information on medicines in the context of the new pharmacovigilance legislation in the EU

Speaker: **Sabine Brosch**, EMA, EU

FDA's Structured Product Labeling (SPL) requirements in the US

Speaker: **Vada Perkins**, FDA, US

10:30 COFFEE BREAK

11:00 **Session 2**

ISO IDMP STANDARDS AT A GLANCE

This session will provide an overview of the key concepts and objectives of each of the IDMP standards and related terminologies including potential use cases. Aspects related to the principles of handling of units of measurements, pharmaceutical dose forms, units of presentation, routes of administration and packaging will be addressed in the overall context.

Data elements and structures for unique identification and exchange of regulated medicinal product information (ISO 11615)

Speaker: **Sabine Brosch**, EMA, EU

Data elements and structures for unique identification and exchange of regulated pharmaceutical product information (ISO 11616)

Speaker: **Vada Perkins**, FDA, US

Data elements and structures for unique identification and exchange of regulated information on substances (ISO 11238)

Speaker: **Ilaria del Seppia**, EMA, EU

Discussant: **Panagiotis Telonis**, EMA, EU

12:30 SANDWICH LUNCH

13:30 **Session 3**

STATUS OF THE ICH M5 HARMONISATION WORK

The achievements of the ICH M5 Expert Working Group and agreed next steps based on the recent face-to-face meeting held in November 2012 will be presented.

Speakers: **Sabine Brosch**, EMA, EU and **Vada Perkins**, FDA, US

14:00 **Session 4**

INDUSTRY'S PERSPECTIVE ON THE IMPLEMENTATION OF ARTICLE 57(2) AND SPL AND EXPECTATIONS FROM THE HARMONISATION ACTIVITIES

This session will provide participants with an insight of how pharmaceutical companies have addressed the implementation of electronic submission of information on medicines from an US and EU perspective and to share expectations on the implementation of the IDMP standards in the context of ICH.

Speakers: **John Kiser**, Abbott, US, Co-chair of the joint EMA/ Pharmaceutical Industry Article 57(2) Implementation Working Group and **Raun Kupiec**, Genzyme Europe, NL

15:00 COFFEE BREAK

15:30 **Session 5**

ARTICLE 57(2) MAINTENANCE AND FREQUENTLY ASKED QUESTIONS

This session will address the next steps towards maintaining the information on medicinal products in accordance with the provisions set out in Article 57(2) and will provide participants with the opportunity to discuss implementation questions.

Next steps towards maintenance of information of medicines in accordance with Article 57(2)

Speaker: **Sabine Brosch**, EMA, EU

Frequently Asked Questions

Speaker: **Ilaria del Seppia**, EMA, EU

Discussants: **John Kiser**, Abbott, **Raun Kupiec**, Genzyme Europe, **Paolo Alcini**, EMA, EU and **Veronika Baker**, EMA, EU

16:30 **END OF THIS INFORMATION DAY**

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Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media, is prohibited without prior written consent from DIA Europe.

HOTEL INFORMATION

Recommended Hotel:

Hilton London Docklands Riverside

265 Rotherhithe Street, London , SE16 5HW, UK

Telephone: +44 (0)20 7231 1001

Fax: +44 (0)20 7231 0599

Email: reservations.docklands@hilton.com

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

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.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

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REGISTRATION FORM

3rd Information Day on the New Identification of Medicinal Products (IDMP)
4 December 2012 | European Medicines Agency, London, UK



ID #12536

Registration includes participant material, coffee breaks and sandwich lunch. This 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

TOTAL AMOUNT DUE:

€ _____

NOTE: PAYMENT DUE 30 DAYS AFTER REGISTRATION AND MUST BE PAID IN FULL BY COMMENCEMENT OF THE EVENT

GROUP DISCOUNT/SME RATES AVAILABLE - PLEASE CONTACT DIA EUROPE FOR MORE INFORMATION

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PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'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 #12536 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.

CANCELLATION POLICY

Cancellations must be made in writing and be received at the DIA Europe office five working days prior to the course start date

Cancellations are subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00

Regrettably, if you do not cancel five working days prior to the course 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 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.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA Europe. If you have not received your confirmation within five working days, please contact DIA Europe.

HOW TO REGISTER

The DIA Europe 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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