

Joint EMA/DIA Information Day on ISO IDMP standards: Achieving Compliance

23 June 2015

European Medicines Agency, London, United Kingdom

PROGRAMME COMMITTEE

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OVERVIEW

In December 2010, new pharmacovigilance legislation (Regulation (EU) No 1235/2010 amending Regulation No 726/2004 and Directive 2010/84/EU amending Directive 2001/83/EC) was adopted by the European Parliament and European Council. Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 require the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines. Specific reference is made to the ISO Identification of Medicinal Product (IDMP) standards that were finalised in 2012 and the implementation guides, which are currently under development at international level. IDMP is a significant undertaking, but it also presents opportunities in terms of how Regulators and Industry manage and share data and particularly as a way to support master data management initiatives.

This Information Day is primarily aimed at providing stakeholders with information to help prepare for the business changes to come and at sharing the EU and FDA strategies for the implementation of the ISO IDMP standards in response to a worldwide demand for internationally harmonised specifications for medicinal products. Topics to be addressed relate to the background of the IDMP standards and legislation, structure of the IDMP standards, international stakeholders perspective and identification of future direction. This forum is providing an opportunity to understand requirements, identify key challenges and to exchange views between regulators, industry, system developers and other stakeholders.

KEY TOPICS

- Current efforts on ISO IDMP Implementation
- Business cases
- Stakeholders' vision and perspective
- Direction of travel

TARGET AUDIENCE

- Marketing Authorisation Holders
- Vendors/Software providers
- IT system developers and data managers

LOCATION

European Medicines Agency

30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Capacity: The event is limited to 110 participants.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



DIA DEVELOP
INNOVATE
ADVANCE

Session Co-Chairs for this Information Day: **Paolo Alcini**, EMA, and **Kevin Horan**, HPRA

Discussants for this Information Day: **Sylvie Beausuroy**, EMA, **Isabel Chicharo**, EMA and **Pedro Batista**, EMA

08:45 **REGISTRATION**

09:15 **WELCOME NOTE**

Francisco Penaranda, EMA; EU

09:30 **SESSION 1**

ISO IDMP IMPLEMENTATION: STAKEHOLDERS' VISION AND PERSPECTIVE FOR THE NEXT 3 YEARS

This session provides the audience with a general introduction to the ISO IDMP Standards, the vision and perspective of both EU Regulators as well as Industry with regards to the ISO IDMP implementation.

ISO Identification of Medicinal Products (ISO IDMP): Introduction and Overview

Vada Perkins, FDA, USA

Industry's vision and perspective for the next 3 years

Andreas Franken, AESGP, DE

EU Regulators' vision and perspective for the next 3 years

Kevin Horan, HPRA, IE

Panel discussion

11:00 **COFFEE BREAK**

11:30 **SESSION 2**

BUSINESS CASES SUPPORTED BY THE ISO IDMP STANDARDS: WIDE PERSPECTIVE

This session provides outlines of business cases that will benefit from the implementation of the ISO IDMP standards as identified in the global regulatory environment and in the context of the EU Open Medicines initiative including a specific EU use case: e-prescription.

Use of ISO IDMP in the regulatory context: identified business cases to support regulatory processes

Ilaria Del Seppia, EMA, EU

Selected examples of business areas that may be fostered by the adoption of the ISO IDMP standards

Andreas Franken, AESGP, DE

Use of ISO IDMP standards to support EU Health initiatives: Open Medicines project

Kevin Horan, HPRA, IE

Discussant: Jos Devlies, Custodix, BE

13:00 **SANDWICH LUNCH**

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14:00 **SESSION 3**

CURRENT EFFORTS ON ISO IDMP IMPLEMENTATION

This session provides the audience with an update on the foreseen timelines for the ISO IDMP Technical Specifications (TSs), the alignment of the ISO IDMP Standards with the ISO IDMP TSs and the HL7 for SPLr7. Furthermore, the foreseen roadmap for the EMA activities on implementing Master Data Management (MDM) System will be presented

ISO IDMP and HL7 status update

Panagiotis Telonis, EMA, EU

EMA Master Data Management (MDM) Road Map

Kepa Amutxastegi, EMA, EU

15:00 **COFFEE BREAK**

15:30 **SESSION 4**

STATUS UPDATE OF THE ACTIVITIES CARRIED BY THE EU ISO IDMP TASKFORCE AND THE FDA

This session is aiming to describe the activities carried by the EU Regulators and FDA for progressing with the ISO IDMP implementation. Updates on the activities carried in the EU in liaison with Industry associations, software vendors, and the EU Regulatory Bodies and the latest outcome of the EU ISO IDMP Task Force discussion will be shared with the audience.

EU ISO IDMP Task Force status report: highlights of the latest discussion

Ilaria Del Seppia, EMA, EU

FDA progress report

Vada Perkins, FDA, US

Panel discussion

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

HOTEL INFORMATION

Attendees are kindly requested to make their own hotel reservation.

Recommended hotel:
Hilton London Docklands Riverside
265 Rotherhithe Street
London SE16 5HW

Tel: +44 20 7231 1001
Fax: +44 20 7231 0599
Email: reservations.docklands@hilton.com

Please contact the hotel directly for the best available rate.

SEND YOUR COMPLETED REGISTRATION FORM TO DIA EUROPE, MIDDLE EAST & AFRICA CONTACT CENTRE TEAM,
E-mail: diaeuropa@diaeurope.org Fax: +41 61 225 51 52 For more information please call +41 61 225 51 51
Online Registration Available at www.diaglobal.org. Go to Meetings and Events

Registration fees*	Fees*
Industry	400.00 EUR <input type="checkbox"/>
Government/Academia/Charitable/Non-Profit (full time)	200.00 EUR <input type="checkbox"/>

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

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Email*

*(Required for confirmation)

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

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

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