FDA Information Day: The New Individual Case Safety Report (ICSR) International Standard and ICH E2B

May 12-13, 2011

Hilton Alexandria Old Town, Alexandria, VA, USA

PROGRAM COMMITTEE

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

Ta-Jen Chen
Project Manager
Office of Information Management, FDA, USA

Gaby L. Danan, MD, PhD
GLD Conseil
Pharmacovigilance Expert, Paris, France

Roger Goetsch, PharmD
AERS Program Specialist
Office of Surveillance & Epidemiology, CDER, FDA, USA

Vada Perkins, MSc, RN
Regulatory Program Management Officer
Office of the Director, CBER, FDA, USA

Lise Stevens
Data Standards Project Manager
Office of the Commissioner, FDA, USA

WHO SHOULD ATTEND

Professionals involved in:

- Clinical Research & Development/Clinical Supplies
- Clinical Safety & Pharmacovigilance
- Electronic Regulatory Submissions/ Document Management
- Information Technology
- Regulatory Affairs

Worldwide Headquarters
Drug Information Association, Inc.
800 Enterprise Road, Suite 200
Horsham, PA 19044, USA

Regional Offices
Basel, Switzerland Tokyo, Japan Mumbai, India Beijing, China

Join Representatives from FDA and EMA to Discuss the ICH Guideline for Clinical Safety Data Management

In May 2005, the revised ICH Guideline for *Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (ICSRs) (E2B(R3))* was released for public consultation. The ICH Steering Committee decided that technical specifications should no longer be developed solely within ICH, but should be created in collaboration with Standards Development Organisations (SDOs) to enable wider interoperability across the regulatory and health care communities. The ICSR is the first topic to go through this process. ICH representatives have been heavily involved in this initiative in addition to other experts from beyond the ICH community. The overall standard is based upon the HL7 ICSR model that is capable of supporting a wide range of product types (e.g. human medicinal products, veterinary products, medical devices, etc.).

ICH proposed to use this standard to meet the reporting requirements for E2B(R3). ICH will define the way that this standard should be used by the publication of an ICH Implementation Guide, which will define the use of the data elements as outlined in the E2B(R3) guideline. In addition, a harmonized approach to ensure backwards and forwards compatibility between the current ICH ICSR message specifications and the new standard – a major aspect during the transition phase until all stakeholders have upgraded their pharmacovigilance systems – will be addressed in the Implementation Guide.

This day and a half workshop will explore how a single, common standard for the ICSR could be advanced.

FEATURED TOPICS

- Status of International Standardization of Clinical Safety Data Management
- Current ICH E2B(R2) Guideline and the HL7 Message Specifications
- How to Adapt the the New ICSR Standard to Your Pharmacovigilance Systems

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Drug Information Association is authorized by IACET to offer 1 CEU for this program.

If you would like to receive a statement of credit, you must attend the program, sign-in at the DIA registration desk each day of the program, and complete the on-line credit request process through My Transcript at www.diahome.org. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests on May 27, 2011.

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LEARNING OBJECTIVES

At the conclusion of this meeting, participants should be able to:

- Discuss the ongoing international standardization work
- Recognize the main changes in comparison to the current ICH E2B(R2) guideline and the HL7 message specifications
- Prepare for the implementation of the new ICSR standard for adaptation in their pharmacovigilance systems

DAY 1 | THURSDAY, MAY 12, 2011

7:15-8:15 AM REGISTRATION AND CONTINENTAL BREAKFAST

8:45-9:00 AM WELCOME AND OPENING REMARKS

PROGRAM CHAIRPERSONS:

Vada Perkins, MSc, RN
Regulatory Program Management Officer
Office of the Director, CBER, FDA, USA

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

9:00-9:45 AM SESSION 1

ICH Process and Collaboration with Standards Development Organizations

This session will provide participants with an understanding of the collaboration of the International Conference on Harmonisation (ICH) with Standards Development Organizations (SDOs). The aim is to enable wider interoperability across the regulatory and healthcare communities. The ICSR is the first topic to go through this new standardization process, whereby the International Organization for Standardization (ISO), Health Level 7 (HL7) and the European Committee for Standardization (CEN) agreed to form a Joint Initiative.

Vada Perkins, MSc, RN
Regulatory Program Management Officer
Office of the Director, CBER, FDA, USA

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

9:45-10:30 AM SESSION 2 - PART I

Differences Between The New ISO ICSR E2B(R3) Standard and The Current ICH ICSR E2B(R2) Guideline

This session aims to describe the key differences between the new ISO ICSR standard and the ICH E2B(R2) guideline/M2 message specifications that currently serve as the basis for the mandatory electronic reporting of adverse reactions in the EU. The impact on the pharmacovigilance business processes will also be highlighted and requirements for future system changes.

Roger Goetsch, PharmD
AERS Program Specialist
Office of Surveillance & Epidemiology, CDER, FDA, USA

Gaby L. Danan, MD, PhD
GLD Conseil
Pharmacovigilance Expert
Paris, France

10:30-11:15 AM REFRESHMENT BREAK

11:15 AM-12:15 PM SESSION 2 - PART II

Differences Between The New ISO ICSR E2B(R3) Standard and The Current ICH ICSR E2B(R2) Guideline

Roger Goetsch, PharmD
AERS Program Specialist
Office of Surveillance & Epidemiology, CDER, FDA, USA

Gaby L. Danan, MD, PhD
GLD Conseil
Pharmacovigilance Expert
Paris, France

12:15-1:15 PM LUNCHEON

1:15-2:30 PM SESSION 3

Overview of The New ISO/HL7 ICSR and Acknowledgement Message Standards

The aim of this session is to provide an overview on how the new ISO/HL7 messages for ICSRs and acknowledgements are structured and organized. Concepts and messaging models will be also described.

Ta-Jen Chen
Project Manager
Office of Information Management, FDA, USA

2:30-3:30 PM SESSION 4 - PART I

ICH E2B(R3) Implementation Guide Overview

This session will focus on the description of the main chapters of the E2B(R3) Implementation Guide, which will describe how the new ICSR standard will be implemented by ICH. In addition, the approach on how to ensure consistency in migrating from the current to the new ICSR standard by all stakeholders will be presented.

Lise Stevens
Data Standards Project Manager
Office of the Commissioner, FDA, USA

3:30-4:00 PM REFRESHMENT BREAK

4:00-4:45 PM SESSION 4 - PART II

ICH E2B(R3) Implementation Guide Overview

Lise Stevens
Data Standards Project Manager
Office of the Commissioner, FDA, USA

4:45-5:00 PM Q & A

5:00 PM END OF DAY ONE

5:00-6:00 PM NETWORKING RECEPTION

DAY 2 | FRIDAY, MAY 13, 2011

7:30-8:30 AM REGISTRATION AND CONTINENTIAL BREAKFAST

8:30-9:30 AM SESSION 5

Regulators Update: FDA/EMA

The first part of this session will provide the latest information about ongoing FAERS activities. The second part of the session will focus on the highlights of the new pharmacovigilance legislation (Regulation (EC) 1235/2010 and Directive 2010/84/EC) and its impact on the reporting of adverse reactions in the EU. The main changes to the EU pharmacovigilance system, EudraVigilance will be also addressed.

Food and Drug Administration: FDA Adverse Event Reporting System (FAERS)

Deborah Yaplee
Senior Program Manager
Center for Biologics Evaluation & Research (CBER), FDA, USA

Jo Wyeth
CDER Business Lead for FAERS
Center for Drug Evaluation & Research (CDER), FDA, USA

European Medicines Agency: The New EU Pharmacovigilance Legislation and its Impact on EudraVigilance and ICSR Reporting

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

9:30-10:30 AM SESSION 6

Lessons Learned: Center for Devices and Radiological Health (CDRH) and Center for Veterinary Medicine (CVM) Experience with ICSR Implementation

Glenn Peterson, PhD
Special Assistant to the Office Director
Business Process Improvement Manager
Office of Surveillance and Compliance
Center for Veterinary Medicine (CVM), FDA, USA

Eugene Reilly
Public Health Analyst
Center for Devices and Radiological Health (CDRH), FDA, USA

10:30-11:00 AM REFRESHMENT BREAK

11:00-12:30 AM SESSION 7

ICH and Regional Planning/Implementation Strategy for The New ICSR

The aim of this session is to discuss the preparation of an FDA and EU Implementation Strategy for the new ICSR standard and the future ISO Identification of Medicinal Products (IDMP) standard, both being strongly interlinked for the purpose of pharmacovigilance. The timelines for the finalization of the standards and the achievement of ICH step 4 of the Implementation Guide will be presented in the context of the overall planning.

Lise Stevens
Data Standards Project Manager
Office of the Commissioner, FDA, USA

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

Vada Perkins, MSc, RN
Regulatory Program Management Officer
Office of the Director, CBER, FDA, USA

12:30 PM MEETING ADJOURNS

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

DIA is a financially independent nonprofit, global, multidisciplinary association that provides a neutral forum for sharing information that optimizes the development and lifecycle management of biopharmaceutical and related products.

FDA Information Day: The New Individual Case Safety Report (ICSR) International Standard and ICH E2B

Event #11030 • May 12-13, 2011

Hilton Alexandria Old Town Hotel

Alexandria, VA, USA

Contact Information

Event Information: Contact Melissa Matta at the DIA office by telephone 215.442.6158, fax 215.442.6199 or email Melissa.Matta@diahome.org.

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Single $211 **Double $231**

Attendees must make their own hotel reservations. Contact the Hilton Alexandria Old Town Hotel by telephone at +1.703.837.0440 and mention the DIA event. The hotel is located at 1767 King Street, Alexandria, VA 22314, USA.

CANCELLATION POLICY: On or before May 6, 2011
Administrative fee that will be withheld from refund amount:
Member or Nonmember = $200
Government or Academia or Nonprofit (Member or Nonmember) = $100
Tutorial (if applicable) = $50

Cancellations must be in writing and be received by the cancellation date above. Registrants who do not cancel by that date and do not attend will be responsible for the full registration fee paid. Registrants are responsible for cancelling their own hotel and airline reservations. You may transfer your registration to a colleague at any time but membership is not transferable. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable.

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Last Name _____

First Name _____ M.I.

Degrees _____ ❑ Dr. ❑ Mr. ❑ Ms.

Job Title _____

Company _____

Address (As required for postal delivery to your location) _____ Mail Stop

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