FDA Information Day:
Individual Case Safety Reports (ICSR)

November 29-30 | Silver Spring, MD

PROGRAM COMMITTEE

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Office of the Director, CBER, FDA

Lise Stevens
Project Manager
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WHO SHOULD ATTEND

Professionals involved in:

- Clinical Supplies
- Safety and Pharmacovigilance
- Regulatory Affairs
- Clinical Research & Development
- Electronic Regulatory submissions
- Information Technology
- Document Management

The new Individual Case Safety Reports (ICSR) standard and the International Conference on Harmonisation (ICH) E2B(R3) Implementation Guide are the next major changes on the horizon. Pharmacovigilance data management will never be the same.

ICSR is a Health Level Seven (HL7) standard for the capture of the information needed to support the reporting of adverse events, product problems or consumer complaints associated with the use of FDA regulated products. HL7 ICSR will be used as the FDA baseline data exchange standard, and is currently being pilot tested to support FDA's transition to a unified electronic environment for managing all FDA-regulated product information for adverse event reports, product and consumer complaints, and product problem reports. HL7 ICSR Release 1 was approved as an American National Standards Institute (ANSI) Standard in 2005, and has been piloted to support electronic medical device reporting (eMDR) for CDRH. The new ICSR Release 3 which has been elaborated as an SDO Joint Initiative between three standards development organizations CEN, HL7, and ISO provides support for adverse event reporting for all FDA regulated products.

Both FDA and EMA, which have been closely collaborating on the standards development, are in the process of preparing new guidance concerning the use of the ICSR for regulatory reporting purposes. The use of MedDRA in the context of the ICSR reporting and FDA's new MedDRA coding policy at LLT level will be also presented.

FDA is organizing this "Information Day" with input from the EMA to provide the latest information about the ISO/HL7 27953 Individual Case Safety Report (ICSR) Release 2 standard, pilot testing and implementation planning. ICSR Release 2 is a joint multi-part International Standards Organization (ISO) and Health Level Seven (HL7) standard for electronic information exchange in support of adverse event reporting, product problems, and consumer complaints. FDA supports ICH adoption of ISO/HL7 27953-2 (Part 2) to support human drug, biologic and vaccine AE reporting from industry.

The achievement of an ICH step 4 ICSR Implementation Guide will be also presented in the context of the overall planning including key comments received as part of the step 3 public consultation and the way they have been resolved. Included in the ICSR implementation strategy is the future ISO Identification of Medicinal Products (IDMP) standard. The IDMP standards support the regulation of medicines and pharmacovigilance activities including ICSR reporting. The important interlink between ICSR and IDMP will be discussed at length.

FEATURED TOPICS:

- Differences between the new (ISO) ICSR E2B(R3) standard and the ICH ICSR E2B(R2) Guideline and how it affects your work
- ICH E2B(R3) Implementation Guide public consultation: Key comments from a US and EU perspective
- Use of MedDRA in the context of the new ICSR reporting – impact on coding and data retrieval
- The new ICSR and IDMP standards – how do they interlink and implementation planning from an FDA and EU perspective

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• Clinical Safety and Pharmacovigilance Certificate Program: 4 Elective Units

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Learning Objectives:
At the conclusion of this meeting, participants should be able to:
- Discuss the ongoing international standardization work on ICSR and IDMP
- Recognize the main new features of the ICSR standards
- Prepare for the implementation of the new ICSR and IDMP standards for adaptation in pharmacovigilance systems

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DAY 1 | THURSDAY, NOVEMBER 29

8:00-8:45 AM REGISTRATION AND CONTINENTAL BREAKFAST

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

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

9:00-9:45 AM SESSION 1

Health Level 7 and the Individual Case Safety Reports (ICSR) and Identification of Medicinal Products (IDMP) Messaging Standards in the Pharmaceutical and Healthcare Domain

Lonnie Smith
Policy Analyst
Data Standards Council and Office of Critical Paths
OC, FDA

This session will provide participants with an overview of the role of HL7 in the international standardization domain with main focus on the new International Organisation for Standardisations (ISO) ICSR and IDMP standards. The impact on the pharmaceutical and healthcare domain and the expected benefits as regards interoperability and improved protection of public health will be presented. This session will be presented on the basis of use cases.

9:45-10:30 AM SESSION 2

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

Gaby L. Danan, MD, PhD
Pharmacovigilance Expert
Consultant, France

Krishna Chary, LL.M, MS
AERS Program Specialist
Office of Surveillance and Epidemiology, FDA

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 electronic reporting of adverse reactions. The expected benefits and the impact on the pharmacovigilance business processes will be highlighted. Requirements for future pharmacovigilance system changes will be also addressed. This session will be presented on the basis of use cases.

10:30-10:45 AM REFRESHMENT BREAK

10:45-11:15 AM SESSION 3

ICH E2B(R3) Implementation Guide Public Consultation: Key Comments from the EU and US Perspective

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

Lise Steven
Project Manager
Bioinformatics Support Staff, FDA

This session focuses on the summary of the main comments received during the public consultation on the ICH E2B(R3) Implementation Guide. Comments will be presented from an industry perspective as collated by EFPIA, as well as from other EU stakeholders and from an FDA perspective.

11:15 AM-12:15 PM SESSION 4

Use of MedDRA: Focus on the New Scope of Adverse Event Reporting

Patrick Revelle
Director
MedDRA MSSO

Sonja Brajovic, MD
Medical Officer
CDER, FDA

The collection of information on suspected adverse reactions will be addressed to include the use of medicinal products within the terms of the marketing authorization as well as from use outside the terms of the marketing authorization, including overdose, misuse, abuse and medication errors and suspected adverse reactions associated with occupational exposure. The appropriate use of MedDRA to facilitate the ICSR coding in these special situations will be also presented.

12:15-1:00 PM LUNCHEON

1:00-1:45 PM SESSION 5

Vaccine Reporting Requirements

Lise Steven
Project Manager
Bioinformatics Support Staff, FDA

This session will focus on US regional requirements for vaccine AE reporting to FDA. The session will describe how to extend relevant sections of the ICH implementation guide and XML schema instance example to support additional data elements and vocabulary based upon the information captured using the FDA/CDC VAERS-1 form.

1:45-2:45 PM SESSION 6

Implementation Planning of the New ICSR Standard

Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardisation in PhV
European Medicines Agency, EU

William Gregory, PhD
Senior Director, Safety and Risk Management
Pfizer Inc., United States

Lise Steven
Project Manager
Bioinformatics Support Staff, FDA

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. Activities related to pilot testing of the new ICSR standard initiated by FDA will be addressed.

2:45-3:15 PM REFRESHMENT BREAK

3:15-4:30 PM SESSION 7

Introduction to the International Standardization and IDMP Topic

The development of the international IDMP standards arising from the ICH topics M5 are close to finalization and implementation. This session will provide an overview of the various activities at international level in order to progress with the finalization of the standards and the drafting of an ICH IDMP Implementation Guide, as well as the activities in relation to the implementation of Article 57(2) requirements in the EU. An industry view will also be provided on the challenges with regard to the impact of product identification on different business processes. The Health Level Seven (HL7) Structured Product Labeling (SPL) and the FDA perspective on how it will work with the ISO IDMP will conclude this session.

International Standardization and the Implementation of Article 57: Current Status and Next Steps

Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardisation in PhV
European Medicines Agency, EU

An Industry View on Identifying Medicinal Products: IDMP, XEVMPD, ICSR and Serialization

William Gregory, PhD
Senior Director, Safety and Risk Management
Pfizer Inc., United States

Health Level Seven (HL7) Structured Product Labelling (SPL): An Overview and Implementation by FDA Implementation

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

4:30 PM DAY 1 ADJOURNS

DAY 2 | FRIDAY, NOVEMBER 30

8:15-9:00 AM REGISTRATION AND CONTINENTAL BREAKFAST

9:00-10:15 AM SESSION 8

ISO IDMP: Substance Identification and How It's Applied in Practice

Lawrence Callahan, PhD
Chemist
OCS, OCPP, Office of the Commissioner
FDA

This session will provide a detailed overview of the ISO FDIS 11238 "Health Informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances" that has been developed to define the concepts required for the unique identification of substances at an international level. Furthermore, the concept of a specified substance has been elaborated allowing capturing more detailed characteristics of substances. This can relate to, for example, intermediate products that contain multiple substances or specified substances of diverse origin and take into account features such as physical forms, constituents, components, marker substances, additives, impurities, manufacturing information, critical production processes, etc. Various examples for different substance classes will be presented to illustrate the specific concepts to be applied according to the FDIS. The use of HL7 messages for the information exchange on substances will be also discussed.

10:15-11:15 AM SESSION 9

ISO IDMP: Medicinal and Pharmaceutical Product Identification and How It's Applied in Practice

This session will be dedicated to providing participants with an overview of the main changes introduced in the ISO FDIS 11615 and 11616 standards. They have been developed to characterize and uniquely identify regulated medicinal products and pharmaceutical products during their entire life cycle from development, to approval and marketing. More specifically, the standards establish definitions and concepts and describe data elements and their structural relationships, which are required for the detailed description and unique identification of medicinal products.

Sabine Brosch, PharmD, PhD
Business Lead, EudraVigilance and International Standardisation in PhV
European Medicines Agency, EU

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

11 :15 AM-12:00 PM SESSION 10

Messaging for IDMP

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

This session will provide participants with an overview of the IDMP messages that support the electronic submission of information on medicines.

12:00 PM MEETING ADJOURNED

REGISTRATION FORM
Register online or fax this page to +1.215.442.6199

FDA Information Day: Individual Case Safety Reports (ISCR)

Event #12029 • November 29-30

Silver Spring Civic Center,
1 Veterans Place, Silver Spring, MD

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Single: $169 **Double: $169**

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Tutorial (if applicable) = $50

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