# HL7 Individual Case Safety Report

**DRUG INFORMATION ASSOCIATION**

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# Session Outline

- Overview of the HL7 Individual Case Safety Report Standard (ICSR)

- Comparison between the HL7 and ICH ICSR

- Next Steps

# HL7 Individual Case Safety Report

- HL7 ICSR is a standard for the exchange for adverse event and product problems
  - Release 1 ANSI accredited HL7 standard for human pharmaceuticals and devices
  - Release 2 Draft Standard for Trial Use (DSTU) covering additional products approved by HL7 January 2007

- Supports reporting of adverse events and product problems to a variety of organizations:
  - Public health: State, local, federal
  - Patient safety or quality improvement organizations
  - Regulatory or other statutory agencies

# ICH and HL7 ICSR Comparison

### ICH ICSR

- Limited scope
  - Related to Pharmacovigilence

- Limited in design
  - Capturing events and outcomes as a result of a substance administration

### HL7 ICSR

- Broader scope
  - Related to Patient Safety

- Broader in design
  - Capturing actions and relationships between patients and associated persons and anyone involved in their healthcare

# ICH and HL7 ICSR Comparison

## ICH ICSR

- Mandatory reporters
  - Supports pre and post market adverse event reporting by mandatory reporters only

- Terminology fixed
  - Clinical information requires the use of MedDRA

## HL7 ICSR

- Mandatory and Voluntary reporters
  - Supports pre and post market adverse event and product problem reporting for both voluntary and mandatory reporters

- Terminology Flexible
  - Clinical information terminology is flexible

# ICH and HL7 ICSR Comparison

## ICH ICSR

- Limited information exchange
  - Designed to support EDI reporting between pharmaceutical companies and regulatory authorities based upon the company's core safety database

- Limited perspective
  - ICH regional perspective, based upon ICH participants: pharmaceutical and regulatory

## HL7 ICSR

- Broader information exchange
  - Designed to support integration of clinical decision support triggers automated reporting based upon stored electronic health record data

- Broader perspective
  - Global perspective and interests: clinical, pharmaceutical, quality improvement, academic, regulatory, vendors

# ICH and HL7 ICSR Comparison

## ICH ICSR

- Limited product support
  - E2B(M) supports human drugs and biologics (excluding vaccines)

  - E2B(R) plans to support human vaccines

- Limited case reporting
  - Individual case reporting

## HL7 ICSR

- Broad product support
  - ✓ Human and Animal Drugs Biologics including vaccines
  - ✓ Medical devices and combination products
  - ✓ Food, food additives, dietary supplements and cosmetics

- Broad case reporting
  - Group case reporting
  - Individual case reporting

# HL7 ICSR Comparison Summary

- Supports a wider variety of product classifications

- Supports flexible implementations

- Supports pre and post market surveillance

- Supports integration with Electronic Health Record systems

# HL7 ICSR Structure

- HL7 ICSR is comprised of three components:

  - ➢ ICSR Base Model
  - ➢ Product Intervention (Use)
  - ➢ Product Information

# HL7 ICSR Structure

- ICSR Base Model captures:

  - Administrative Information
  - Investigative Subject and Associated Person Information
  - Reaction and Case Narrative
  - Medical and Medications History
  - Clinical Trial Enrollment

# HL7 ICSR Structure

- **Product Intervention** captures:

  ➢Information about how the product was used or administered to the investigative subject or associated persons

  ➢Release 2 created a generic structure with flexibility to support requirements for a variety of product types

# HL7 ICSR Structure

- **Product Information** captures:

  - ➢ Detailed information about the product (such as its ingredients, manufacturer, packaging, approval and characteristics)

  - ➢ Release 2 generic model supports a wider variety of product classifications including combination products

# HL7 ICSR Supports FDA Initiatives

- The HL7 ICSR supports FDA vision of a consolidate infrastructure for report receipt and cross-product analyses by:

  ➤ Providing a common format for consistent data capture

  ➤ Providing flexibility for harmonizing domains using common terminology

# HL7 ICSR Next Steps
# FDA

➢Continue pilot testing with ICSR Release 1 for electronic device reporting

➢Continue agency harmonization of data elements and terminology requirements

➢Coordinate HL7 ICSR Release 2 DSTU testing

# HL7 ICSR Next Steps National and International

➢ Evaluation of HL7 ICSR in the Health Information Technology Standards Panel (HITSP)

➢ Evaluation of HL7 ICSR in ISO activity

➢ Continue participation in HL7 and federal government initiatives to harmonize ICSR with clinical trial reporting:
- ✓ NIH Federal Adverse Event Task Force (FAET)
- ✓ HL7 *RCRIM and *CDISC *BRIDG Harmonization

- • NIH = National Institutes of Health
- • RCRIM = Regulated Clinical Research Information Management Technical Committee
- • CDISC = Clinical Data Interchange Standards Consortium
- • BRIDG = Biomedical Research Integrated Domain Group

# HOW CAN YOU CONTRIBUTE?

- Become active in HL7 or subscribe to the HL7 Patient Safety Special Interest Group List server

- Contribute requirements to the ISO/HL7/CEN/ICH Consortium project through your appropriate PhRMA representatives

- Participate in FDA DSTU Testing

# CONTACT INFORMATION

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