

# ***Introduction to Postmarketing Drug Safety Surveillance:***

## ***Pharmacovigilance in FDA/CDER***

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# Disclaimer

- The following presentation is for educational purposes only. Questions regarding product specific labeling should be referred to the Center/Division responsible for regulation of that product.
- Opinions expressed in this presentation are those of the speakers and do not necessarily reflect official positions or policy of the FDA.
- The speakers have nothing to disclose.

# Objectives

- Define Pharmacovigilance
- Understand regulatory requirements for reporting postmarketing safety information
- Describe how adverse event reports are collected and analyzed by FDA/CDER/DPV
- Understand electronic reporting of Individual Case Safety Report (ICSR)
- Understand an ICSR and its components

# Pharmacovigilance

The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.



\* The Importance of Pharmacovigilance, World Health Organization 2002

# Divisions of Pharmacovigilance

- Evaluate the safety of drug and therapeutic biologic products
- Advance public health by detecting and analyzing safety signals from multiple data sources, utilizing evidence-based methods
- Recommend appropriate regulatory actions, including labeling changes
- Communicate relevant safety information



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# Outline

- Spontaneous Adverse Event Reports
- FDA Adverse Event Reporting System (FAERS)

# Spontaneous Reports

- A communication from an individual (e.g., health care professional, consumer) to a company or regulatory authority
- Describes a suspected adverse event(s)
- Passive and voluntary reports



## Factors Affecting Reporting

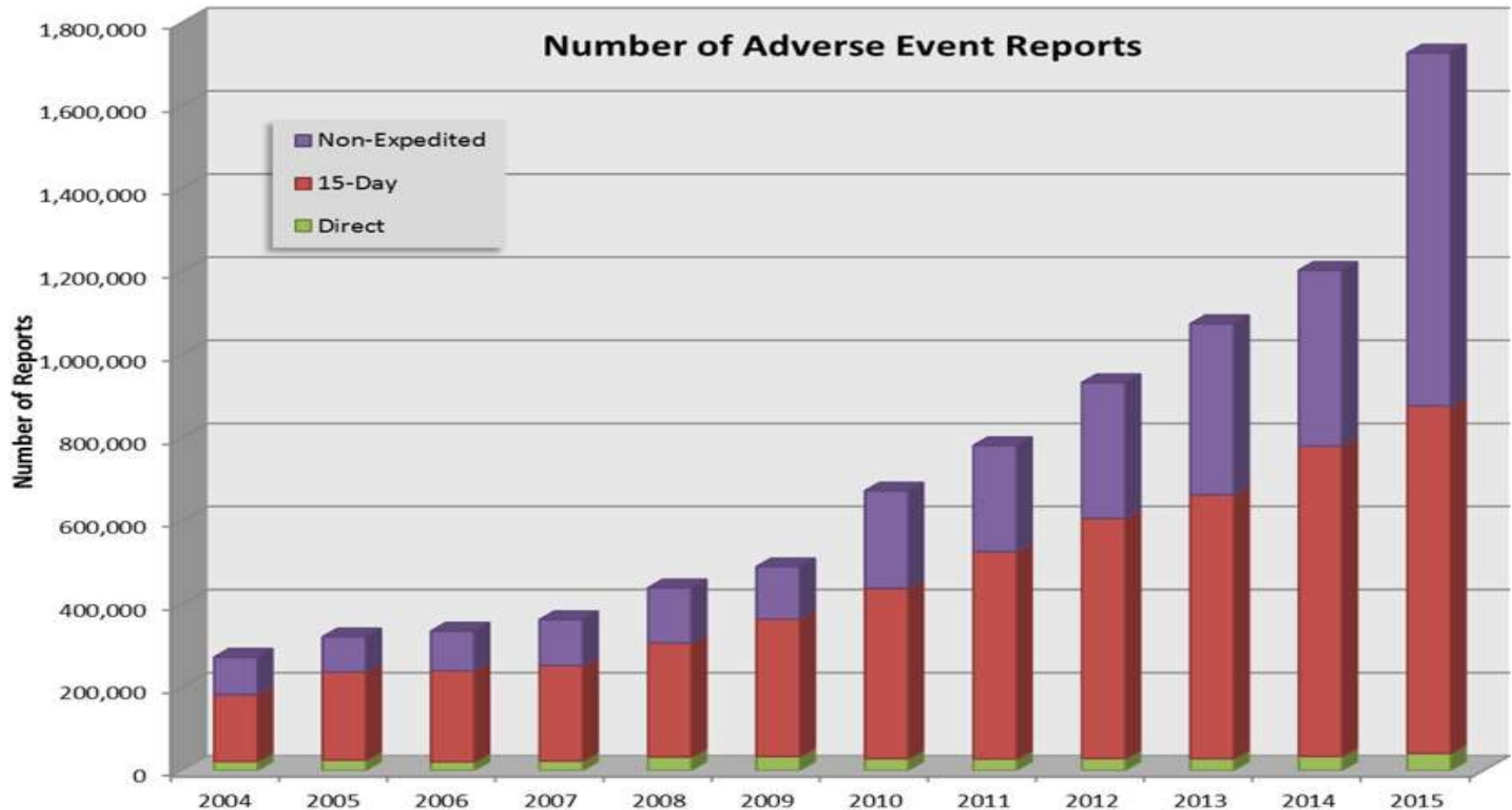
- Media attention
- Litigation (class action lawsuits)
- Nature of the adverse event
- Type of drug product and indication
- Length of time on market
- Extent and quality of manufacturer's surveillance system
- Prescription or over-the-counter (OTC) product status
- Reporting regulations

# FDA Adverse Event Reporting System

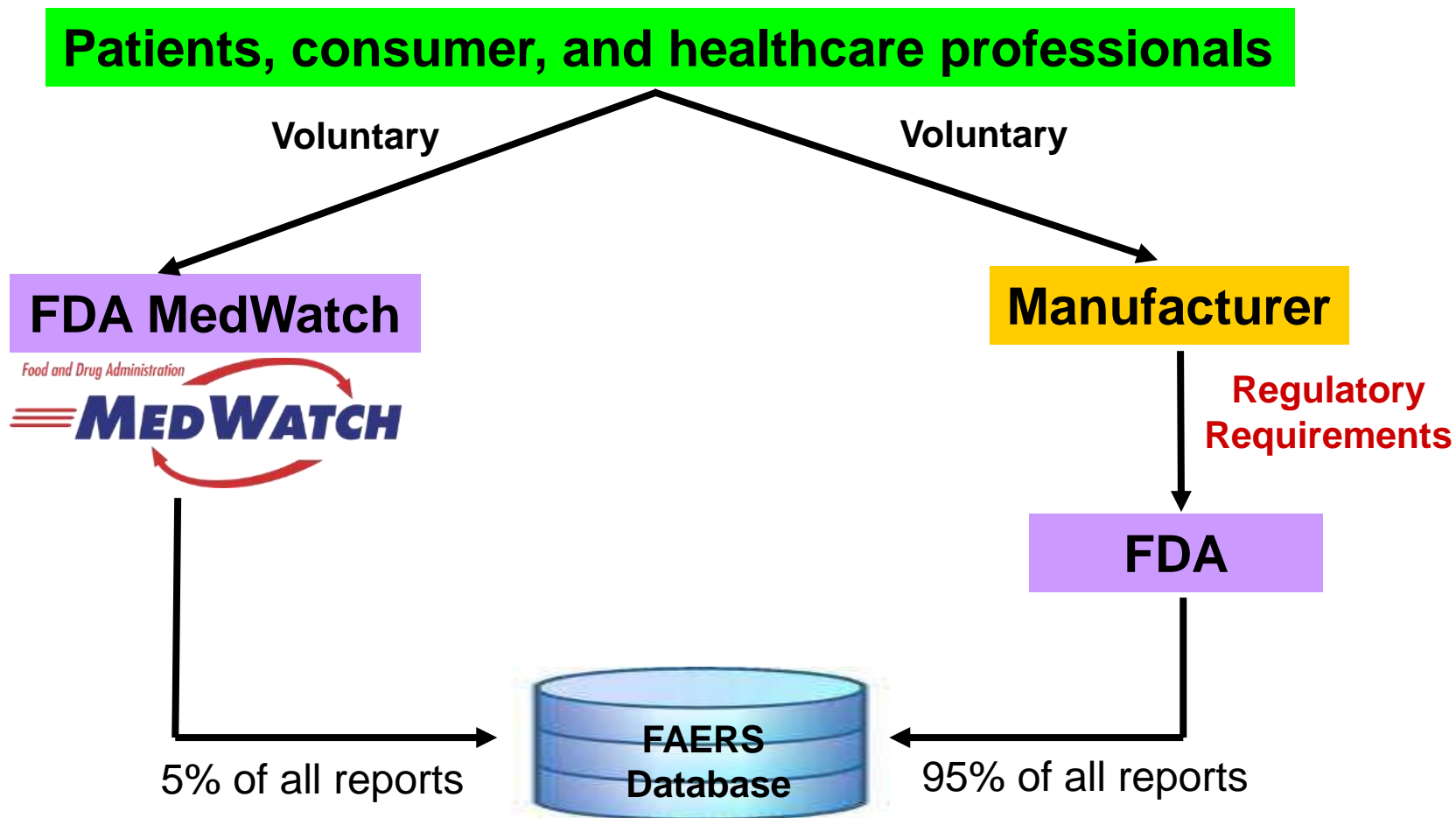
- Computerized database
- Spontaneous reports
- Contains human drug and therapeutic biologic reports
- > 12 million reports since 1969
- Over 1.6 million new reports in 2015



# Number of Adverse Event Reports Entered into FAERS



# How Postmarketing Reports Get to FDA



# Postmarketing Safety Reporting Requirements

- Under 21 CFR 314.80 postmarketing safety reports must be submitted to the agency for the following:
  - **15-day Alert reports:** Serious and unexpected adverse experience from all sources (domestic and foreign)
  - **Periodic Adverse Events Reports:** Domestic spontaneous adverse events that are:
    - Serious and expected
    - Non-serious and unexpected
    - Non-serious and expected
    - Quarterly for the first 3 years then annually

# Serious and Unexpected Adverse Event

- **Serious**
  - Death
  - Life-threatening adverse experience
  - Inpatient hospitalization – new or prolonged
  - Persistent/significant disability/incapacity
  - Congenital birth defect
  - Other serious: based upon appropriate medical judgment, they may jeopardize the patient and require intervention to prevent a serious outcome
- **Unexpected**
  - Adverse event that is not listed in the current labeling for the drug product

# FAERS Strengths

- Includes all U.S. marketed products
- Includes all uses
- Includes broad patient populations:
  - elderly, children, pregnant women, co-morbidities
- Especially good for events with a rare background rate
- Useful for events that occur shortly after exposure
- Detection of events not seen in clinical trials (“signal generation”)
- Identification of reporting trends, possible risk factors, at risk populations, and other clinically significant emerging safety concerns

## FAERS is less useful for:

- Events with high background rates
- Issue that goes beyond required Medwatch data elements
- Comparative incidence rates
- Comparing drugs in the same class
- Adverse events that could also be manifestations of the disease for which the drug is indicated



# Challenge Question #1

DRG-D2S1-1

View Votes
Edit
End Poll

The incidence of adverse drug events can be determined through spontaneous reporting systems.

<input type="radio"/> True	<div></div>	0%	(0)
<input type="radio"/> False	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

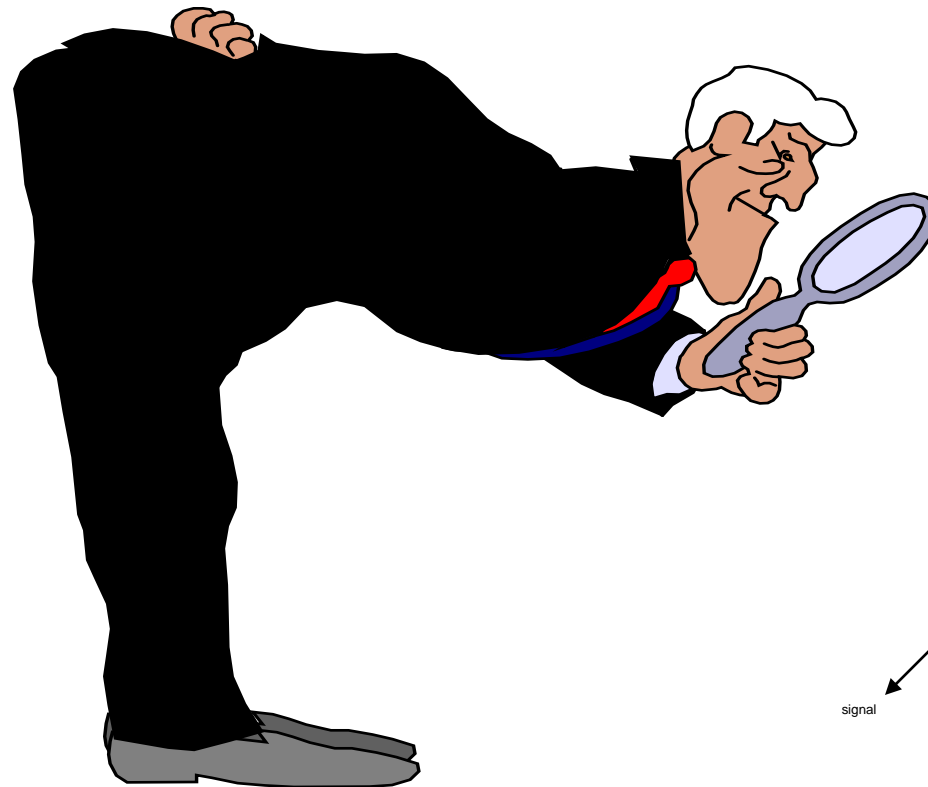
# Objectives

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# Outline

- Signal Detection
- Components of a Good Case Report
- Communicating Safety Issues

# Safety Signal Detection



Did you  
see it??

signal

# What is a Safety Signal?


- Reported information on a possible causal relationship between an adverse event and a drug
- The relationship being previously unknown or incompletely documented
- Usually supported by multiple case reports
- New unlabeled adverse events
- An observed increase in a labeled event OR a greater severity or specificity
- New interactions
- Newly identified at-risk population

# Sources of Possible Safety Signals

- Routine pharmacovigilance
  - FAERS
  - Data mining
  - Periodic Safety Update Reports from drug manufacturers
- Study results
- Medical literature
- Media
- New Drug Application (NDA) database
- Outside inquiry
- Foreign Regulatory Agencies
- Others



## Challenge Question #2

DRG-D2S1-2


View Votes
Edit
End Poll

**A safety signal could be:**

<input type="radio"/> New, previously unknown, adverse event	<div></div>	0%	(0)
<input type="radio"/> New drug interaction	<div></div>	0%	(0)
<input type="radio"/> An observed change in quantity, severity or the affected populations of a known adverse event	<div></div>	0%	(0)
<input type="radio"/> All of the above	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

# Components of a Good Case Report



## Case #1

A health care worker reported a male patient started Drug X at 5 mg daily for type 2 diabetes on February 11, 2011. On an unknown date, the patient developed liver failure; additional information was not provided.

## Case #2: Best Case Representative

- 59-year-old male with type 2 diabetes, hyperlipidemia, and hypertension. No history of liver disease.
- Started Drug X on February 11, 2011.
- Other medications: simvastatin and lisinopril.
- Labs drawn on Feb 11 revealed Liver enzymes, INR, creatinine, and bilirubin were within normal limits.
- No alcohol use.
- 8 weeks after starting Drug X patient presented to ER with 5 day history of jaundice, dark urine, and nausea/vomiting.
- He was admitted to ICU and subsequently diagnosed with acute liver failure.
- Drug X stopped upon admission.
- Viral hepatitis was ruled out.
- 7 days after stopping the medication, all lab values returned to normal.

# Components of a Good Postmarketing Report

- Description of adverse event
- Suspected and concomitant product therapy details (e.g., dose, dates of therapy)
- Patient characteristics (e.g., age, sex), baseline medical condition, co-morbid condition, family history, other risk factors
- Documentation of the diagnosis
- Clinical course and outcomes
- Relevant therapeutic measures and laboratory data
- Dechallenge and rechallenge information
- Reporter contact information
- Any other relevant information

*Guidance for Industry - Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, March 2005*

# Communicating Safety Issues



# Communicating Safety Issues to the Public and Internationally

- MedWatch Safety Alerts
- Postmarket Drug and Biologic Safety Evaluations (FDAAA 915)
- Potential Signals of Serious Risks/New Safety Information Identified from FAERS (FDAAA 921)
- Published literature and scientific meetings
- Video and teleconferences with foreign regulatory agencies:
  - EMA: European Medicines Agency
  - 4-Way: Canada, Australia, New Zealand, (Singapore in writing)

# MedWatch: The FDA Safety Information and Adverse Event Reporting Program




Your FDA gateway for clinically important safety information and reporting serious problems with human medical products.

MedWatch The FDA Safety Information and Adverse Event Reporting Program

Subscribe to MedWatch Safety Alerts

Safety Information

Reporting Serious Problems to FDA

 **Report a Problem**

 **Safety Information**

 **Stay Informed**

## What's New

- [Heart Sync Inc. Multi-function Defibrillation Electrodes: Device Correction - Connector Incompatibility with Philips FR3 and FRx Defibrillator Units May result in a delay in therapy.](#) Posted 12/03/2014
- [Gel-E Donut and Squishon 2 Products by Children's Medical Ventures: Recall - Potential Mold Contamination](#) UPDATED 12/02/2014. Recall classified as Class I. Possibility of fungal infection should patients come in contact with mold. Originally posted 11/14/2014

## FDA Approved Safety Information

- [DailyMed \(National Library of Medicine\)](#)  
Current Drug Prescribing Information. (NOTE: Drugs marked "unapproved" on this site have not been reviewed by FDA for safety and efficacy, and their labeling has not been approved.)
- [Medication Guides](#)  
Paper handouts that come with many prescription medicines. Medication Guides address issues specific to particular drugs and drug classes. They contain FDA-approved information that can help patients avoid serious adverse events.
- [Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System \(FAERS\)](#)
- [Postmarket Drug and Biologic Safety Evaluations](#)  
Evaluations performed 18 months after drug approval, or after its use by 10,000 individuals.

## Resources for You

- [2014 Safety Alerts for Human Medical Products](#)
- [Contact Information For Voluntary Adverse Event Reporting](#)
- [MedWatchLearn - Teaching students, health professionals, and consumers how to report problems to FDA](#)
- [Medical Product Safety Educational Resources](#)
- [Consumer-Friendly Reporting Form 3500B \(PDF - 1.2MB\)](#)

# References



- Arthur N et al. The Importance of Pharmacovigilance – Safety Monitoring of Medicinal Products. WHO 2002.
- Drug Safety Communications: <http://www.fda.gov/Drugs/DrugSafety/ucm199082.htm>
- FDA Patient Safety News: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/index.cfm>
- Guidance for Industry- Postmarketing Safety Reporting for Human Drug and Biological Products including Vaccines, March 2001:  
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/ucm074850.htm>
- Guidance for Industry- Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment, March 2005: <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126834.pdf>
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program:  
<http://www.fda.gov/Safety/MedWatch/default.htm>
- MedWatch Medical Product Safety Information:  
<http://www.fda.gov/Safety/MedWatch/SafetyInformation/default.htm>
- MedWatch Safety Alerts: <http://www.fda.gov/Safety/MedWatch/ucm287881.htm>
- MedWatch Safety Alert RSS Feed:  
<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/MedWatch/rss.xml>
- Postmarket Drug Safety Information for Patients and Providers (FDAAA 915):  
<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm>
- Postmarketing Drug and Biologic Safety Evaluations: (FDAAA 915):  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/ucm204091.htm>
- Potential Signals of Serious Risks/New Safety Information Identified from AERS (FDAAA 921):  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082196.htm#QuarterlyReports>

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## Outline

- Introduction to FAERS
- Why an electronic ICSR submission requirement
- Submission Methods
- Submission of Periodic Safety Reports
- Future state of electronic submission
- References

# Electronic Reporting of ICSRs

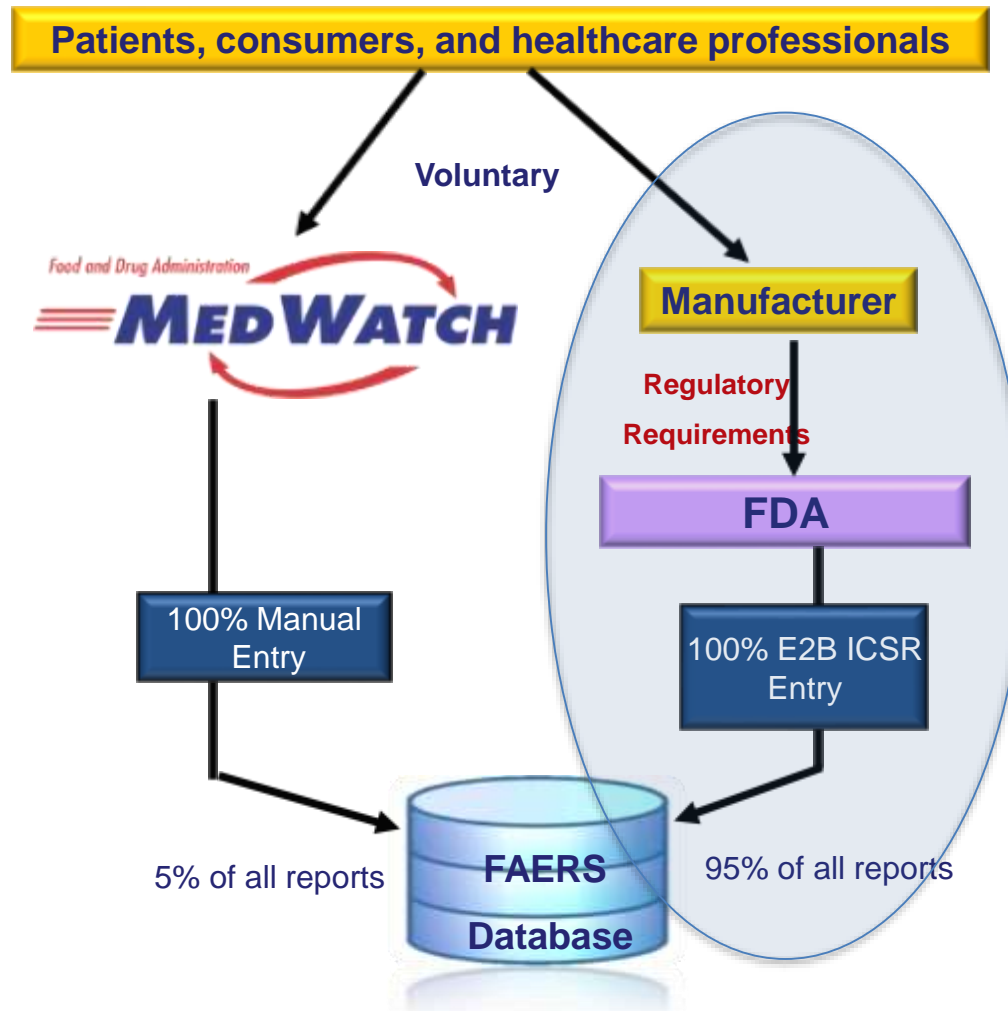
## **FDA Adverse Event Reporting System (FAERS)**

- FDA's postmarketing safety surveillance database for drugs and therapeutic biologics
- FDA uses FAERS data to monitor, identify and analyze adverse event and medication errors
- FDA staff in CDER and CBER regularly examine the FAERS database as part of routine safety monitoring
- When a safety signal is identified from FAERS data, it is further evaluated



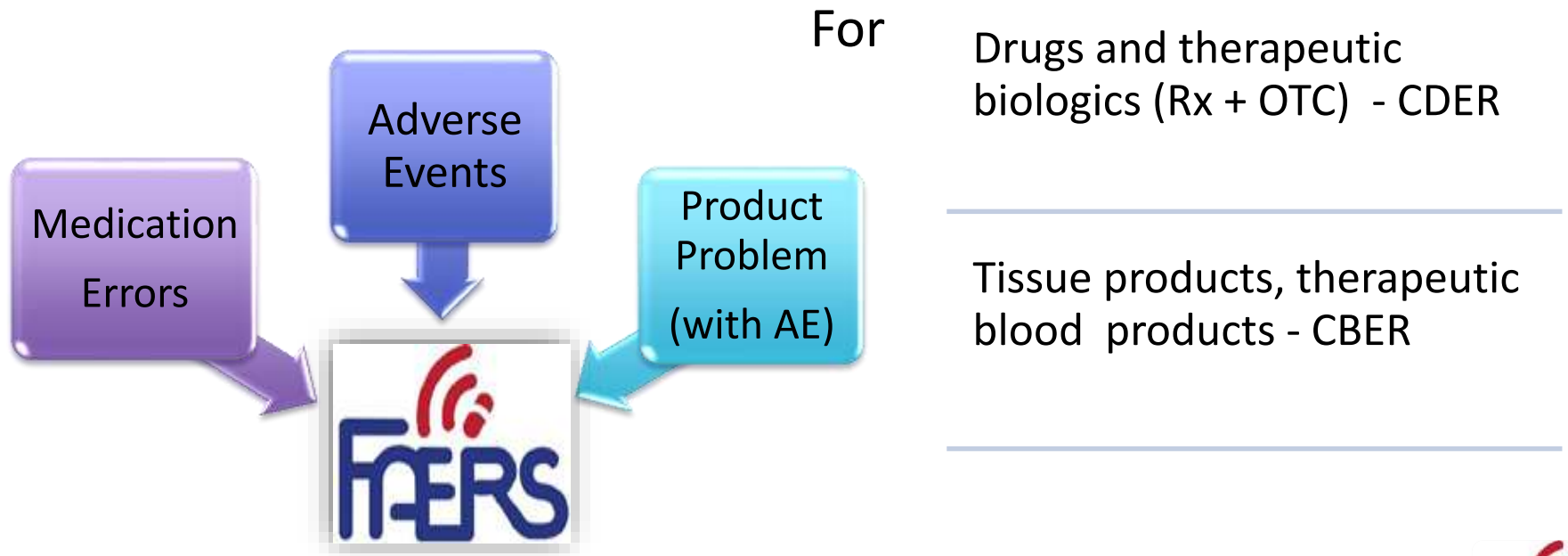
# Electronic Reporting of ICSR

How post-marketing adverse event reports get to FDA



# Electronic Reporting of ICSR

What Reports are in the FAERS Database?



# Electronic Reporting of ICSRs

## Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements

- **Submit safety reports in an electronic format** that FDA can process, review, and archive
- **Improve** the Agency's systems for **collecting and analyzing** postmarketing safety reports
- **Enable** Agency to **more rapidly review** postmarketing safety reports, **identify and evaluate** emerging safety problems, and **disseminate** safety information in support of FDA's public health mission
- Electronic submission of ICSRs **enhances** global pharmacovigilance by **facilitating electronic transmission and exchange of appropriate information** from ICSRs among regulatory bodies and regulated entities through use of **common data elements and transmission standards**

# Electronic Reporting of ICSRs

## Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements

### Document Information

**Date Posted:**

May 27, 2015

**RIN:**

0910-AF96

**CFR:**

21 CFR Parts 310, 314, 329, and 600

**Federal Register Number:**

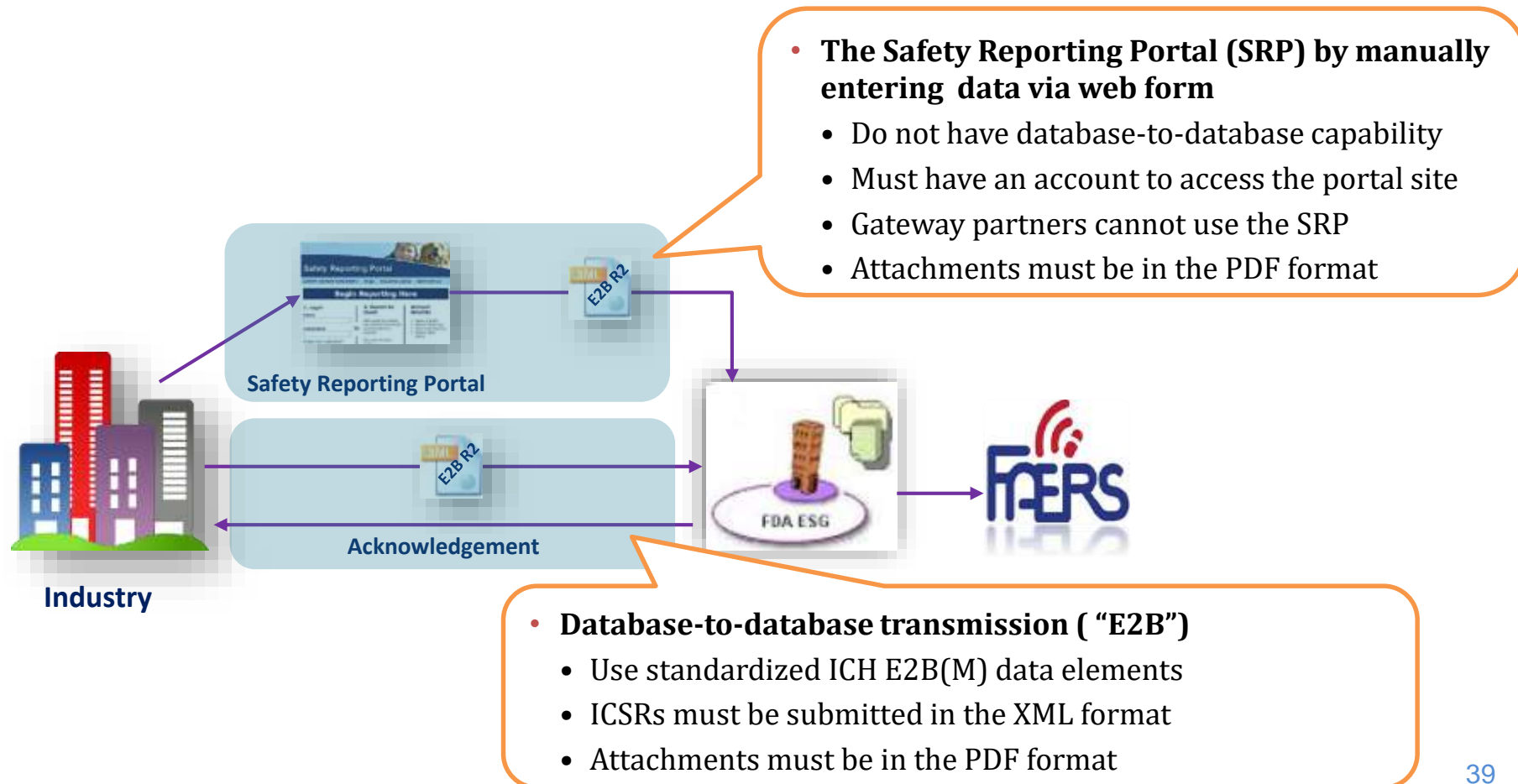
2015-12753

<https://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0334-0009>

# Electronic Reporting of ICSRs

## Submission Methods

- There are two options for submitting ICSRs electronically



# Safety Reporting Portal (SRP)

## Safety Reporting Portal

ABOUT THE PORTAL | SAFETY REPORT DIRECTORY | FAQs | RELATED LINKS | CONTACT US

### The Safety Reporting Portal

The Safety Reporting Portal (SRP) streamlines the process of reporting product safety issues to the Food & Drug Administration (FDA) and the National Institutes of Health (NIH).

Whatever your role, (manufacturer, health care professional, researcher, public health official, or concerned citizen), when you submit a safety report through this Portal, you make a vital contribution to the safety of America's food supply, medicines, and other products that touch us all.

### Who Should Submit a Safety Report?

Organizations and people in certain professional roles, such as the following, may be required by law to submit safety reports under some circumstances:

- Food Manufacturers, Processors, Packers, and Holders
- Researchers
- An applicant of an approved drug product or a manufacturer, distributor or packer listed on the label of any drug product
- Drug Manufacturers
- Dietary supplement manufacturers, packers, and distributors

Others, including health care providers, public health officials, and other professionals, as well as consumers and concerned citizens, may voluntarily submit reports if they encounter safety issues with a product and/or unanticipated harmful effects that they believe are related to a product.

[Learn more about mandatory and voluntary reporting.](#)

### Begin Reporting Here

#### 1. Login

EMAIL

PASSWORD

[Forgot your password?](#)

☐ Remember me

[Log In](#)

#### 2. Report As Guest

Not ready to create an account but would like to submit a report?

Or

You can do that here.

[Report as Guest](#)

#### Account Benefits

- Save a draft
- Easier follow up
- View submissions
- Faster data entry

[Create Account](#)

### Reports You Can Submit Through this Portal

FDA safety issues involving:

- Marketed human drug and therapeutic biologics
- Human or animal reportable foods
- Animal drugs
- Animal foods
- Tobacco products
- Dietary supplements

NIH safety issues involving:

- NIH gene-transfer research

For other issues, [find out where to submit your report.](#)

PRIVACY POLICY | FREEDOM OF INFORMATION ACT | ACCESSIBILITY | DISCLAIMER

[Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.]

## Safety Reporting Portal

Welcome Guest HOME | FAQs | RELATED LINKS | CONTACT US | FEEDBACK | HELP

### New Guest Report

You have chosen to use this portal as a guest reporter.

Reports submitted as a guest cannot be saved. Therefore, please plan to complete your report in full during this session. If you prefer to save your report and complete it at a later time, please return to the home page and create an account.

**\*Select the option that best describes what you want to do:**

- ☒ Start a new report
- ☐ Follow-up on a report previously submitted as a guest portal user.
- ☐ Follow-up on a report previously submitted as a logged in user.
- ☐ None of the above

**\*Which of the following best describes you?**

- ☐ Reportable Food Registry Report (mandatory): A food facility or responsible party that manufactures, processes, packs, or holds foods who is submitting a reportable food report.
- ☐ Reportable Food Registry Report (voluntary): A federal, state, or local public health official who is submitting a reportable food report involving human and/or animal food.
- ☐ Pet Food Report: A veterinarian or veterinary staff member who is submitting a product problem and/or adverse event report involving pet food.
- ☐ Pet Food Report: A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving pet food.
- ☐ Livestock Food Report: A veterinarian or other professional who is submitting a product problem and/or adverse event report involving livestock food.
- ☐ Livestock Food Report: A consumer or concerned citizen who is submitting a product problem and/or adverse event report involving livestock food.
- ☐ Animal Drug Report: A marketing authorization holder (manufacturer) for an animal drug who is submitting a report on a product problem and/or an adverse event.
- ☐ Tobacco Product Report: A healthcare professional submitting a product problem and/or health-related problem report involving a tobacco product.
- ☐ Tobacco Product Report: A consumer or concerned citizen who is submitting a product problem and/or health-related problem report involving a tobacco product.
- ☐ Dietary Supplement Report (mandatory): A dietary supplement manufacturer, packer, or distributor who is submitting a mandatory serious adverse event report.
- ☐ Dietary Supplement Report (voluntary): A consumer, concerned citizen, or healthcare professional who is submitting a report about an illness, injury, or product problem associated with dietary supplement(s) or a manufacturer, packer, or distributor who is submitting a dietary supplement voluntary adverse event and/or product problem report.
- ☐ Gene Research Study Report: A clinical trial primary investigator or researcher who needs to report an adverse event involving a gene research study.
- ☒ Marketed Human Drug and Therapeutic Biologics Report (mandatory): An applicant, manufacturer, packager, and distributor of human drugs and biological products, other than vaccines who is submitting on a product problem and/or adverse event.
- ☐ None of these describe me.

Please contact the [CDER.srp@hhs.gov](mailto:CDER.srp@hhs.gov) to request access.

Thank you for your interest.

[English Version](#) [Español](#)



- 

## Safety Reporting Portal

[HOME](#)
[FAQS](#)
[RELATED LINKS](#)
[CONTACT US](#)
[FEEDBACK](#)

### My Reports

Draft Reports - Click column header to sort the column

Date Saved (EST)	Report ID	Title	Report Type Description
09/13/2013 09:17:09 AM	4430 (R)	SPHR - Medicated Soap	SPHR Created by: Ann Goldberg
09/30/2013 07:17:09 AM	6648 (F)	Allergy Product X - Rash adverse event	SPHR/MCN US-ABOPHARMA-1251896 Created by: Joe Smith

[« <Page 1 of 1 > »](#)

### Submitted Reports Available for Follow-Up

Submitted as of  ICSR Number (please enter the number only):

### Submitted Reports. Click column header to sort the column

Date Submitted (EST)	Report ID	ICSR #	Title	Report Type Description
09/13/2013 09:17:09 AM	4431 (R)	120208 (R)	Prescription drug X - adverse event	SPHR - MCN US-ABOPHARMA Submitted by: Ann Goldberg
09/13 11:38:22 AM	4432 (R)	1201896 (R)	Allergy Product X - Rash	SPHR - MCN US-ABOPHARMA Submitted by: Joe Smith

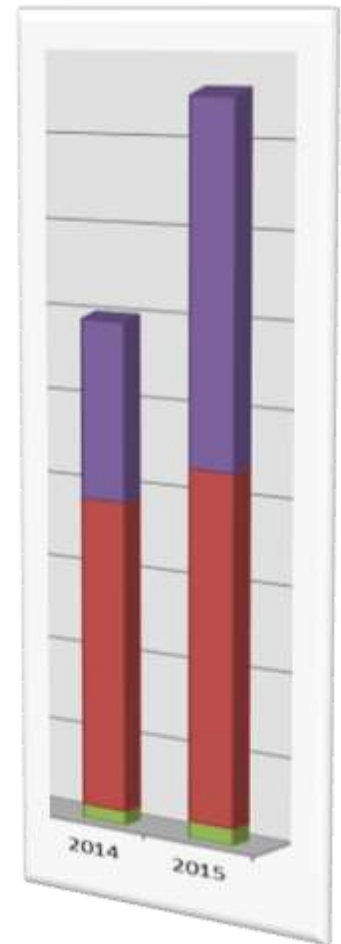
[View](#)
[View PDF](#)

# Electronic Reporting of ICSRs

## Submitting Periodic Safety Reports (PSR)

Periodic safety reports are comprised of a **descriptive portion** and **non-expedited ICSRs** (21 CFR 314.80 and 600.80), regardless of the format.

- **Descriptive Portion:**
  - Use **Electronic Common Technical Document (eCTD)** specifications to submit the descriptive portion electronically.
  - **Indicate** in the descriptive portion that the **ICSRs have been submitted electronically** as XML files to the FDA Electronic Submissions Gateway (ESG) or via the Safety Reporting Portal (SRP).
- **Non-expedited ICSRs:** must be submitted as described in the options **on or before** the periodic safety report due date. Do NOT submit expedited ICSRs previously submitted.



# Electronic Reporting of ICSRs

## Future state of electronic submission

- “FDA Regional Implementation Specifications for ICH E2B(R3) Implementation: Postmarket Submission of Individual Case Safety Reports (ICSRs) for Drugs and Biologics, Excluding Vaccines” posted on June 23, 2016
- Follow core ICH E2B R3 with a few regional requirements
- Regional Elements
  - Ethnicity
  - Race
  - Drug descriptor
    - Combination
    - Compounding

## Challenge Question #3

**DRG-D2S1-3**

View Votes

Edit

End Poll

**Methods to submit ICSR:**

<input type="radio"/> a. Database-to-database	<div></div>	0%	(0)
<input type="radio"/> b. Safety Reporting Portal	<div></div>	0%	(0)
<input type="radio"/> c. Paper MedWatch	<div></div>	0%	(0)
<input type="radio"/> d. a and b	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

## Challenge Question #4

**DRG-D2S1-4**

View Votes

Edit

End Poll

Periodic report are comprised of two parts: 1) Descriptive portion, and 2) Non-expedited ICSRS

<input type="radio"/> True	<div></div>	0%	(0)
<input type="radio"/> False	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results



# Electronic Reporting of ICSRs

## References

- FDA Adverse Event Reporting System (FAERS) - Electronic Submission  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115894.htm>
- FDA issues final rule on postmarketing safety report in electronic format  
<http://www.regulations.gov/#!documentDetail;D=FDA-2008-N-0334-0009>
- Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments  
<http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM153588.pdf>
- Steps to Submitting E2B(R2) ICSRs Electronically in the XML Format  
<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm115914.htm>
- Electronic Common technical Document (eCTD)  
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>

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# Understanding an ICSR

## Outline

- During Electronic Submission
- Case Information
- Version of ICSRs
- Patient Characteristics
- Drug(s) Information
- Other Required ICSR Administrative Elements
- Reporter of the Information
- Narrative Case Summary
- Conclusion

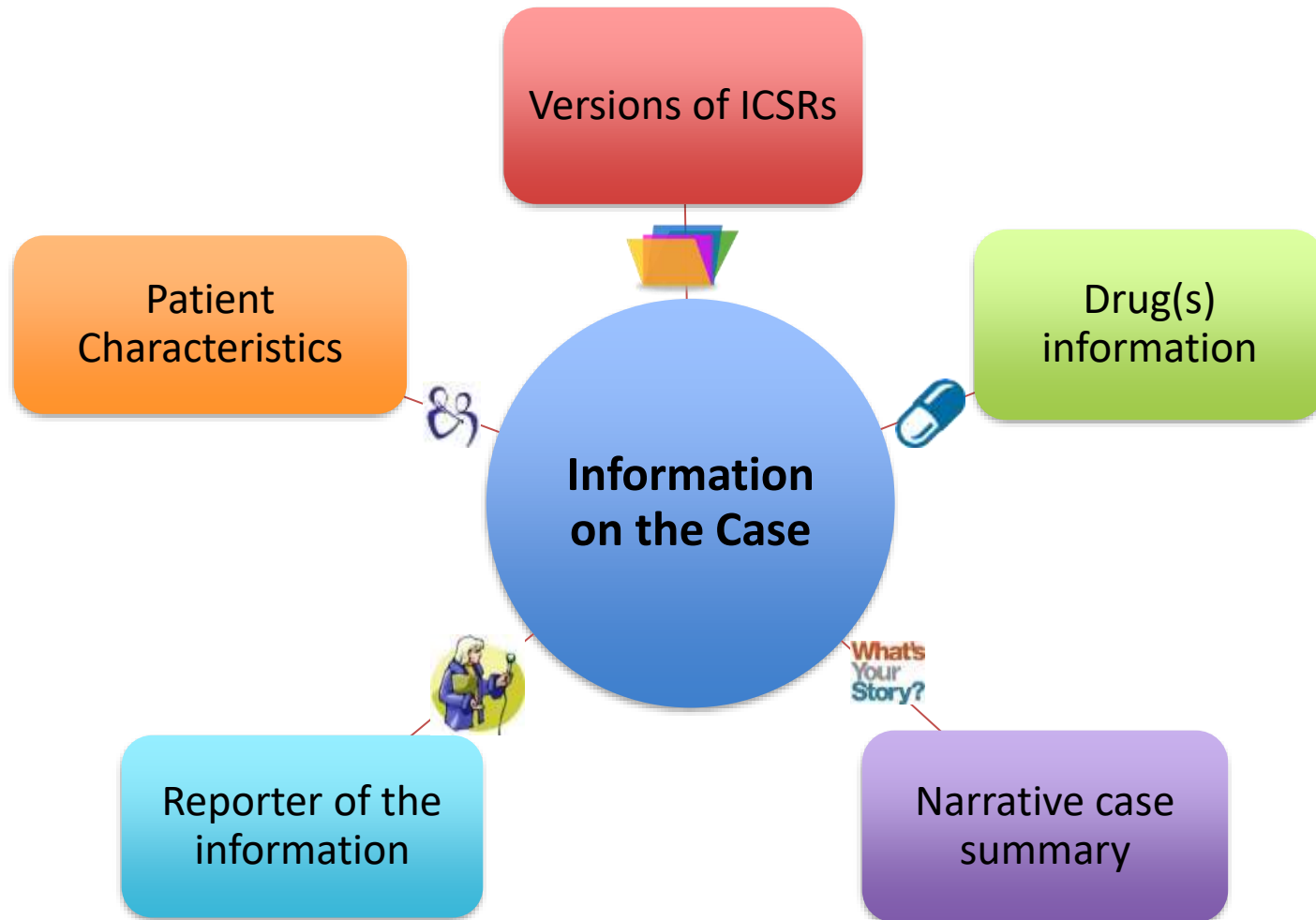


# Understanding an ICSR

## During Electronic Transmission

- Standardized data elements for the electronic transmission of Individual Case Safety Reports (ICSRs)
- Scope
  - All types of ICSRs regardless of source or destination
  - ICSRs referring to post-marketing safety reports
  - FAERS is only for CDER and CBER (therapeutic biologics and tissue reports)
    - Tissue reports are excluded from the mandatory electronic reporting rule

# Understanding an ICSR





# Understanding an ICSR

## Versions of ICSRs

- FAERS receiving ICSRs with the same Manufacturer Control Number (MCN) creates a case with versions
- MCN should be used for the life of the case, to avoid duplications
- All reports should have a Mfr. received date, even for literature reports
- Sender is the manufacturer never the Contract Research Organization (CRO), who are processing and sending the reports to FDA
- Sender organization should not change after approval to submit electronically



# Understanding an ICSR

## Patient Characteristics

- Different ways to include the same data. Example age information can be sent as:
  - Date of birth and date of reaction
  - Age at the time of reaction
  - Patient age group
- Note: Age should be provided by the most **precise** available data element.

# Understanding an ICSR



## Patient Characteristics (continued)

- If the information is provided in the narrative regarding the patient characteristics, it should be included in the patient section.
- Example:

– Narrative: A 50 year old female weighting 60 Kg experienced a rash when exposure to this drug.

Diagram illustrating the extraction of patient characteristics from a narrative:

- Age: 50 year
- Sex: female
- Weight: 60 Kg

**Patient ID should not contain patient's personal information, only initials or unique identifier**

# Understanding an ICSR



## Drug(s) information

- The first drug listed in the ICSR should be the primary suspect drug with the appropriate application number:

Type of Application	Recommended Format
NDA / ANDA	NDA or ANDA 012345
STN/BLA/PLA	STN or BLA or PLA 123456
Rx No Application	000000
Non-Rx No Application	999999
Compounding (503B)	COMP99



# Understanding an ICSR



## Drug(s) information (continued)

- No pre-marketing IND reports as primary suspect drug
- If the clinical trial involves a suspect drug which has an approved application the case has to be submitted to FAERS after the blind is broken with the application number, if it meets the criteria and regulations of a post-marketing safety report.
- No study reports until the blind is broken

# Understanding an ICSR



## Other Required ICSR Administrative Elements

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
A.1.9	<fulfillexpeditecriteria>	1N	1=yes (expedited) 2=no (non-expedited)
A.1.0.1	<safetyreportid>	100AN	Sender's (Case) Safety Report Unique Identifier
A.1.10.1	<authoritynumb>	100AN	Regulatory authority's case report number
A.1.10.2	<companynumb>	100AN	Other sender's case report number
A.3.1.2	<senderorganization>	60AN	Sender identifier





# Understanding an ICSR

## Reporter of the information

### Multiple reporters

- First one is the primary reporter

### Medically confirmed flag

- One of the reporters is a physician

### Literature and Study Reports

- Provide the title of the literature or study
- Link the literature document as a PDF to the ICSR

### Occupation of each reporter

- Whether the information was provided by consumer or medical personnel?

# Understanding an ICSR

## Narrative case summary

- Narrative is limited to **20,000 characters**
- Should **describe the story** of the adverse event(s) and product(s) associated from onset to the outcome
- Follow-up narrative should contain the **complete narrative with the additional information** in the body
- All ICSRs (expedited and non-expedited) **should have a full narrative**

**What's  
Your  
Story?**

# Understanding an ICSR

## Conclusion

- Format of ICSRs includes:
  - provisions for transmitting all the relevant data elements useful for assessing an individual adverse drug reaction report
- Not every data element is applicable for every transmission
- A substantial number of non-required data elements may not be known for each case
- The most current information on the case available to the sender must be provided

# Questions



Please complete the session survey:

[surveymonkey.com/r/DRG-D2S2](https://surveymonkey.com/r/DRG-D2S2)



# **Closing Thoughts...**

# **Thank You!**

