

Electronic Submission

FDA Safety Report Type Flag Requirement

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CDER | US FDA

New FDA Safety Report Type Flag Requirement for FAERS Submissions
February 19, 2021

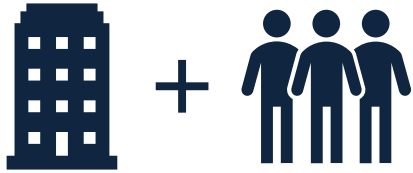
Learning Objectives

- Discuss and define the FDA Safety Report Type Flag requirement
- Highlight benefits associated with the requirement
- Locate the revised technical specification Guide
- Communicate implementation considerations
- Connect with FDA for assistance/feedback



FAERS Submission Requirements + Benefits

What is FAERS?



Industry and public stakeholders submit individual case safety reports (ICSR) for human drug and nonvaccine biologic products



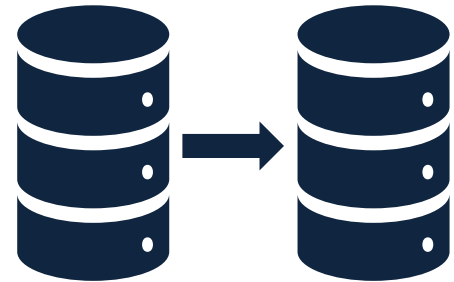
FDA stores ICSRs in a safety surveillance database



Staff monitor database for safety signal and further evaluate if FDA action is warranted

Database to Database Transmission (E2B)

- ✓ Submissions must use standardized International Conference on Harmonisation (ICH) E2B standards
- ✓ ICSRs must be submitted in the eXtensible Markup Language (XML) format
- ✓ Attachments must be in PDF format



Safety Reporting Portal

- ✓ Must have an account to access the portal
- ✓ Must not be a Gateway partner
- ✓ Attachments must be in PDF Format



New Reporting Requirement

 ICSRs currently do not include safety report type in submissions

New Regional R2 Elements

Element Name: FDA Safety Report Type

Element ID: A.1.FDA.16

Element Tag: <fdasafetyreporttype>

Element Length: 1

Element Data Type: N

Conformance: Required

Element Allowed Values:

- 1 = IND Safety Report
- 2 = IND Exempt BA/BE Safety Report
- 3 = Postmarketing Safety Report

Benefits

- Distinguish premarket (IND and IND-Exempt BA/BE) safety reports from postmarketing safety reports
- Determine which reports are posted publicly easily

ICSRs from postmarketing studies required under 314.80 (e) must be marked as “3” regardless of whether the study was conducted under an IND

Updated DTD 2.1 & 2.2

```
<!-- A.1.FDA.16 FDA Safety Report Type -->
<!--
Field ref: A.1.FDA.16
Field title: FDA Safety Report Type
Field name: fdatasafetyreporttype
Field length: 1N
Field values:
1=IND Safety Report
2=IND Exempt BA/BE Safety Report
3=Postmarketing Safety Report
Comment: The FDA Safety Report Type data element distinguishes
premarket (IND and IND-Exempt BA/BE) safety reports from
postmarketing safety reports and is used to determine which reports
are posted publicly.
Note: This is a mandatory data element
-->
<!ELEMENT fdatasafetyreporttype (#PCDATA)>
<!ATTLIST fdatasafetyreporttype
    %lang.att;
>
```




Implementation Considerations

AS2 Header Attributes

Current State: Post market reports (does not apply to pre-market)

- Destination: “CDER”
- Attribute values: “**AERS**” for XML’s and “**AERS_ATTACHMENTS**” for PDF’s

Proposed Future State: For IND reports, new header attributes need to be setup/configured to route the files into the new folders (does apply to pre market ICSRs)

- Destination remains the same (“CDER”)
- Attribute values: “**AERS_PREMKT**” for XML’s and “**AERS_ATTACHMENTS_PREMKT**” for PDF’s



AS2 Routing IDs

Current State: Post market reports (does not apply to pre-market)

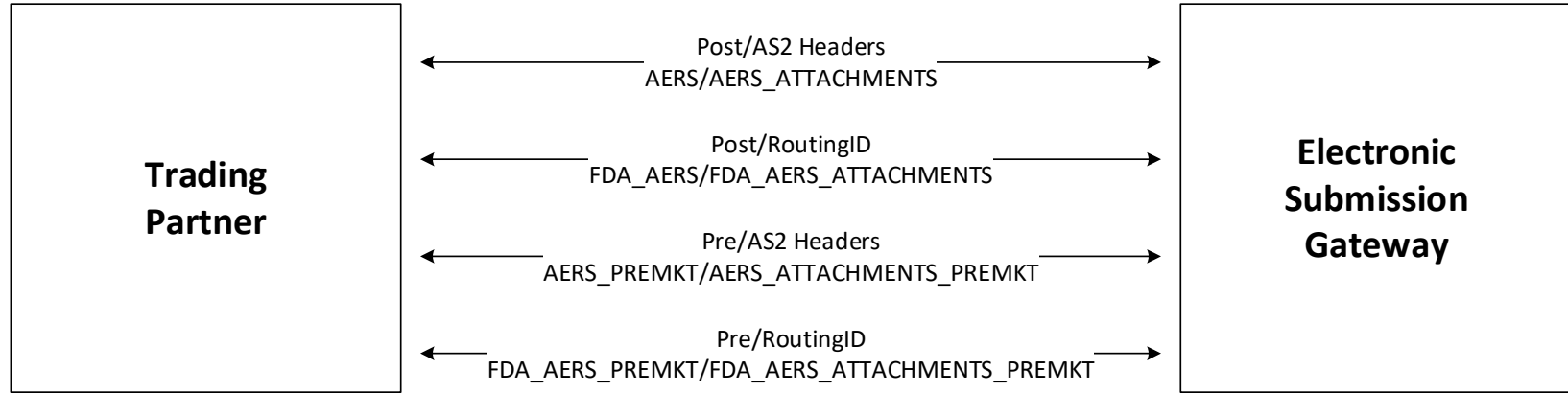
- Routing ID's: **"FDA_AERS"** for XML's and **"FDA_AERS_ATTACHMENTS"** for PDF's

Proposed Future State: For IND reports, new Routing ID's would need to be setup and corresponding configuration changes required (would apply to pre market ICSRs).

- Routing ID's: **"FDA_AERS_PREMKT"** for XML's and **"FDA_AERS_ATTACHMENTS_PREMKT"** for PDF's



Routing Mechanism



Submission Rules

The submission rules define the condition that shall result in a negative acknowledgement and not be accepted by FAERS

Table 11. Submission Rules and Acknowledgement Status

Data Element	DTD Descriptor 2.1/2.2	Rejection Rule Description	Acknowledgement
A.1.FDA.16	<fdasafetyreporttype>	Data value 1 or 2 submitted using AS2 Header where XML file: AERS or Routing ID where XML file: FDA_AERS	reportacknowledgment code (B.1.8) = 02
A.1.FDA.16	<fdasafetyreporttype>	Data value 3 submitted using AS2 Header where XML file: AERS_PREMKT or Routing ID where XML file: FDA_AERS_PREMKT	reportacknowledgment code (B.1.8) = 02



New Technical Specification Document

Navigate to your favorite search engine

(ex. <http://www.google.com>) & Search for “*FAERS Electronic Submissions*”

The image shows a browser window with a Google search page. The search bar contains the text "FAERS Electronic Submissions", which is highlighted with a red box. Below the search bar, the search results are displayed. The first result is highlighted with a red box and includes the following text:

www.fda.gov › drugs › fda-adverse-event-reporting-sy...
FDA Adverse Event Reporting System (FAERS) Electronic ...
Jan 6, 2021 — **Electronic Submissions** of IND Safety Reports to **FAERS** · Database-to-Database Transmission (“E2B”). **Submit** attachments to ICSRs through the ...

Below this, other search results are visible, including:

- www.fda.gov › drugs › news-events-human-drugs › ele...
Electronic Submission of Adverse Event Reports to FDA ...
These meetings will focus on enhancements to **electronic submission** of Individual Case Safety Reports (ICSRs) in **FAERS** using ICH E2B(R3) standards. Dates ...
- www.fda.gov › media › download | PDF
E2B(R3) - FDA
Oct 11, 2019 — What are the methods for **submitting** ICSRs to **FAERS** by sponsors? A. **Electronic Submission** Gateway. B. Safety Reporting Portal. C. MedWatch ...
- www.fda.gov › media › download | PDF
Electronic Submission of IND Safety Reports Technical ... - FDA
For an IND safety report to be successfully processed in **FAERS**, it needs to have one valid IND number in the appropriate ICH E2B data field. Sponsors should ...

FDA Adverse Event Reporting System (FAERS) Electronic Submissions



Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

[FDA Adverse Event Reporting
System \(FAERS\): Latest
Quarterly Data Files](#)

[FDA Adverse Event Reporting
System \(FAERS\) Public
Dashboard](#)

[FDA Adverse Event Reporting
System \(FAERS\) Electronic
Submissions](#)

Updates for Electronic Submission of Individual Case Safety Reports (ICSRs) to FAERS

Premarketing Safety Reporting

Starting June 28, 2021, FDA will begin accepting electronic submissions for IND Safety Reports to FAERS. In preparation for the upcoming receipt of IND Safety Reports, FDA has posted the following documents regarding the electronic submission of certain investigational new drug applications (INDs) safety reports for drugs and biological products to FAERS. These documents are posted to help prepare systems for electronic submissions of IND safety reports.

- [Providing Regulatory Submissions in Electronic Format: IND Safety Reports - Draft Guidance for Industry \(October 2019\)](#)
- [Electronic Submission of IND Safety Reports - Technical Conformance Guide \(October 2019\)](#)
- [The revised technical specifications document Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments \(December 2020\). FDA has revised this document to include data elements, descriptors, and descriptor values for reporting certain IND safety reports as individual case safety reports \(ICSRs\).](#)**

For investigational drugs and biological products without an established name (i.e. INK or USAN name), or if the established name exceeds established E2B character lengths, prior to submission of IND safety reports to FAERS, the sponsor should submit to the IND a general correspondence in eCTD format to inform FDA of how the product name will be submitted within the established E2B character lengths. Please refer to the [Electronic Submission of IND Safety Reports - Technical Conformance Guide \(October 2019\)](#) for further information.

Postmarketing Safety Reporting

Starting June 28, 2021, FDA is implementing a new mandatory regional data element for the electronic submission of ICSRs. The new regional data element, A.1.FDA.16 (FDA Safety Report Type), will distinguish the safety report type as IND Safety Reports, IND Exempt

Content current as of:
02/03/2023

Regulated Product(s)
Drugs

Navigate to <https://www.fda.gov>



The image is a screenshot of a web browser displaying the official website of the U.S. Food and Drug Administration (FDA). The browser's address bar shows the URL <https://www.fda.gov>, which is highlighted with a red rectangular box. The website's header features the FDA logo on the left and search and menu icons on the right. The main content area is dominated by a large banner image. This banner is a composite of three parts: on the left, several glass vials containing clear liquids; in the center, a 3D model of a coronavirus particle with its characteristic red, spiky surface; and on the right, a close-up of a person's arm being injected with a vaccine by a healthcare professional wearing gloves. Below the banner, a white text box contains the following information:

FEATURED

FDA Takes Action to Address Coronavirus Disease 2019 (COVID-19)

FDA issues Emergency Use Authorization for second COVID-19 vaccine.

Select "Drugs"

FEATURED

FDA Takes Action to Address Coronavirus Disease 2019 (COVID-19)

FDA issues Emergency Use Authorization for second COVID-19 vaccine.

FDA COVID-19 RESPONSE

FDA is working with U.S. Government partners, including CDC, and international partners to address the pandemic.

[COVID-19 information](#)

PRODUCTS WE REGULATE

[Food](#)

[Drugs](#)

[Medical Devices](#)

[Radiation-Emitting Products](#)

[Vaccines, Blood, and Biologics](#)

[Animal and Veterinary](#)

[Cosmetics](#)

[Tobacco Products](#)

Navigate to <https://www.fda.gov/drugs>



Drugs | FDA

https://www.fda.gov/drugs

An official website of the United States government [Here's how you know >](#)

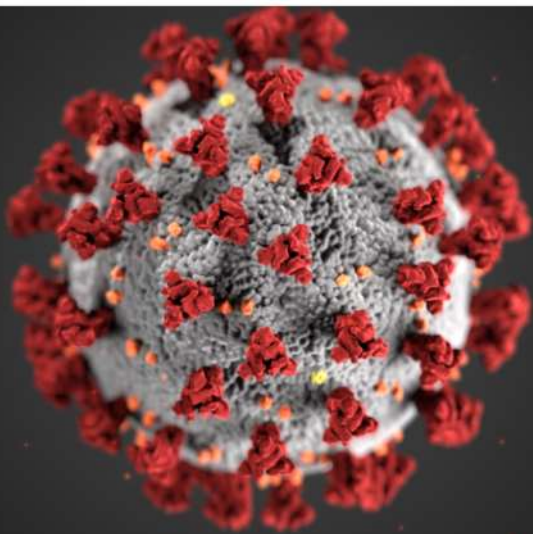
FDA U.S. FOOD & DRUG ADMINISTRATION

Search Menu

IN THIS SECTION

← Home

Drugs



CDER is engaged in essential COVID-19 activities to protect and promote public health

Ranging from the acceleration of development for treatments for COVID-19, maintaining and securing drug supply chains, providing guidance to manufacturers, advising developers on how to handle clinical trial issues, and keeping the public informed

[Learn More](#)

Select “Guidance, Compliance, and Regulatory Information”

The screenshot shows a web browser window with the URL <https://www.fda.gov/drugs>. The page features three event cards at the top:

- Drug Master File (DMF) Workshop**: MARCH 3-4, 2021. Via Webcast. Mar 3 - Will provide guidance on the DMF submission process and expectations.
- FDA to share current thinking on Non-alcoholic Steatohepatitis (NASH)**: Jan 29 - Webinar to focus on NASH drug development and clinical trial efforts.
- Webinar to provide overview of Over-the-Counter Monograph Reform**: Jan 27 - Will discuss safety issues: identification, evaluation and response.

Below the events is a section titled "NAVIGATE THE DRUGS SECTION" with a grid of eight navigation links:

- Drug Information, Safety, and Availability**: Medication Guides, Drug Safety Communications, Shortages, Recalls
- Drug Approvals and Databases**: Drugs@FDA, Orange Book, National Drug Code, Recent drug approvals
- Drug Development and Review Process**: Drug applications, submissions, manufacturing, and small business help
- Guidance, Compliance, and Regulatory Information**: Guidances, warning letters, drug compounding, international information, registration and listing
- Regulatory Science and Research**: CDER research programs, initiatives, and resources
- Emergency Preparedness**: Prepare and respond to natural disasters, nuclear and chemical attacks
- Updates, News, and Events**: Recent approvals, meetings, workshops, blogs, podcasts, stay connected
- About the Center for Drug Evaluation and Research (CDER)**: Our role, mission, organization, history, leadership, job openings

The "Guidance, Compliance, and Regulatory Information" link is highlighted with a red rectangular border.

Navigate to

<https://www.fda.gov/drugs/guidance-compliance-regulatory-information>



Guidance, Compliance, & Regulatory Information



- Guidance, Compliance, & Regulatory Information
- Human Drug Exports
- Good Review Practices | GRPs
- Electronic Drug Registration and Listing System (eDRLS)
- CDER FOIA Electronic Reading Room
- CDER International Program
- Enforcement Activities | FDA
- Guidances (Drugs)
- Human Drug Compounding

Popular Items

- Access to Product Samples: The CREATES Act
- Affordable Care Act (ACA 6004)
- "Deemed to be a License" Provision of the BPCI Act
- Human Drug Compounding
- Drug Compliance Programs
- FDA Drug Competition Action Plan
- Guidances (Drugs)
- CDER International Program
- Newly Added Guidance Documents
- Product-Specific Recommendations for Generic Drug Development
- Nicotine-Containing Products
- Notice to Industry: Postmarketing Requirements - Postmarket studies and clinical trials

Content current as of:
07/21/2020

Regulated Product(s)
Drugs

Select "Surveillance: Post Drug-Approval Activities"

The screenshot shows the FDA website's navigation menu on the left and a list of resources on the right. The 'Surveillance: Post Drug Approval Activities' link in the navigation menu is highlighted with a red box. The list of resources on the right includes various acts and programs related to drug regulation.

Navigation Menu (Left):

- Human Drug Imports
- Good Review Practices | GRPs
- Electronic Drug Registration and Listing System (eDRLS)
- CDER FOIA Electronic Reading Room
- CDER International Program
- Enforcement Activities | FDA
- Guidances (Drugs)
- Human Drug Compounding
- Human Drug Imports
- Laws, Acts, and Rules
- Postmarketing Requirements and Commitments: Introduction
- Surveillance: Post Drug Approval Activities**

Resources (Right):

- Access to Product Samples: The CREATES Act
- Affordable Care Act (ACA 6004)
- "Deemed to be a License" Provision of the BPCI Act
- Human Drug Compounding
- Drug Compliance Programs
- FDA Drug Competition Action Plan
- Guidances (Drugs)
- CDER International Program
- Newly Added Guidance Documents
- Product-Specific Recommendations for Generic Drug Development
- Nicotine-Containing Products
- Notice to Industry: Postmarketing Requirements - Postmarket studies and clinical trials
- Office of Compliance
- The Office of Prescription Drug Promotion (OPDP)
- Prescription Drug Labeling Resources
- Report a Product Quality Issue
- Sunscreen Innovation Act (SIA)
- Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval
- Warning Letters and Notice of Violation Letters to Pharmaceutical Companies

Resources For You

- Compliance Policy Guide, Chapter 4 – Human Drugs
- Manual of Policies & Procedures (CDER)
- Sunscreen Innovation Act (SIA)

Select "Questions and Answers on FDA's Adverse Event Reporting System (FAERS)"



Surveillance: Post Drug-Approval Activities

https://www.fda.gov/drugs/guidance-compliance-regulatory-information/surveillance

An official website of the United States government

U.S. FOOD & DRUG ADMINISTRATION

Search Menu

Home / Drugs / Guidance, Compliance, & Regulatory Information / Surveillance: Post Drug-Approval Activities

Surveillance: Post Drug-Approval Activities



Surveillance: Post Drug-Approval Activities

[Report a Product Quality Issue](#)

[Postmarket Drug and Biologic Safety Evaluations](#)

[Office of Prescription Drug Promotion](#)

[Prescription Drug Advertising and Promotional Labeling](#)

[Questions and Answers on FDA's Adverse Event Reporting System \(FAERS\)](#)

A vital part of CDER's mission is to monitor the safety and effectiveness of drugs that are currently available to the American people. To meet this goal, FDA has in place postmarketing programs that monitor marketed human medical products for unexpected adverse events. These programs alert the Agency to potential threats to the public health. Agency experts then identify the need for preventive actions, such as changes in product labeling information and, rarely, re-evaluation of an approval decision.

Content current as of:
02/05/2018

Select "FDA Adverse Event Reporting System (FAERS) Electronic Submissions"

Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

Home / Drugs / Guidance, Compliance, & Regulatory Information / Surveillance: Post-Drug-Approval Activities / Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

Share Tweet LinkedIn Email Print

Content current as of: 06/04/2018

Regulated Product(s): Drugs

Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

- FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files
- FDA Adverse Event Reporting System (FAERS) Public Dashboard
- FDA Adverse Event Reporting System (FAERS) Electronic Submissions**

What is FAERS?

The FDA Adverse Event Reporting System (FAERS) is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA. The database is designed to support the FDA's post-marketing safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation (ICH E2B). Adverse events and medication errors are coded using terms in the [Medical Dictionary for Regulatory Activities \(MedDRA\)](#) [terminology](#).

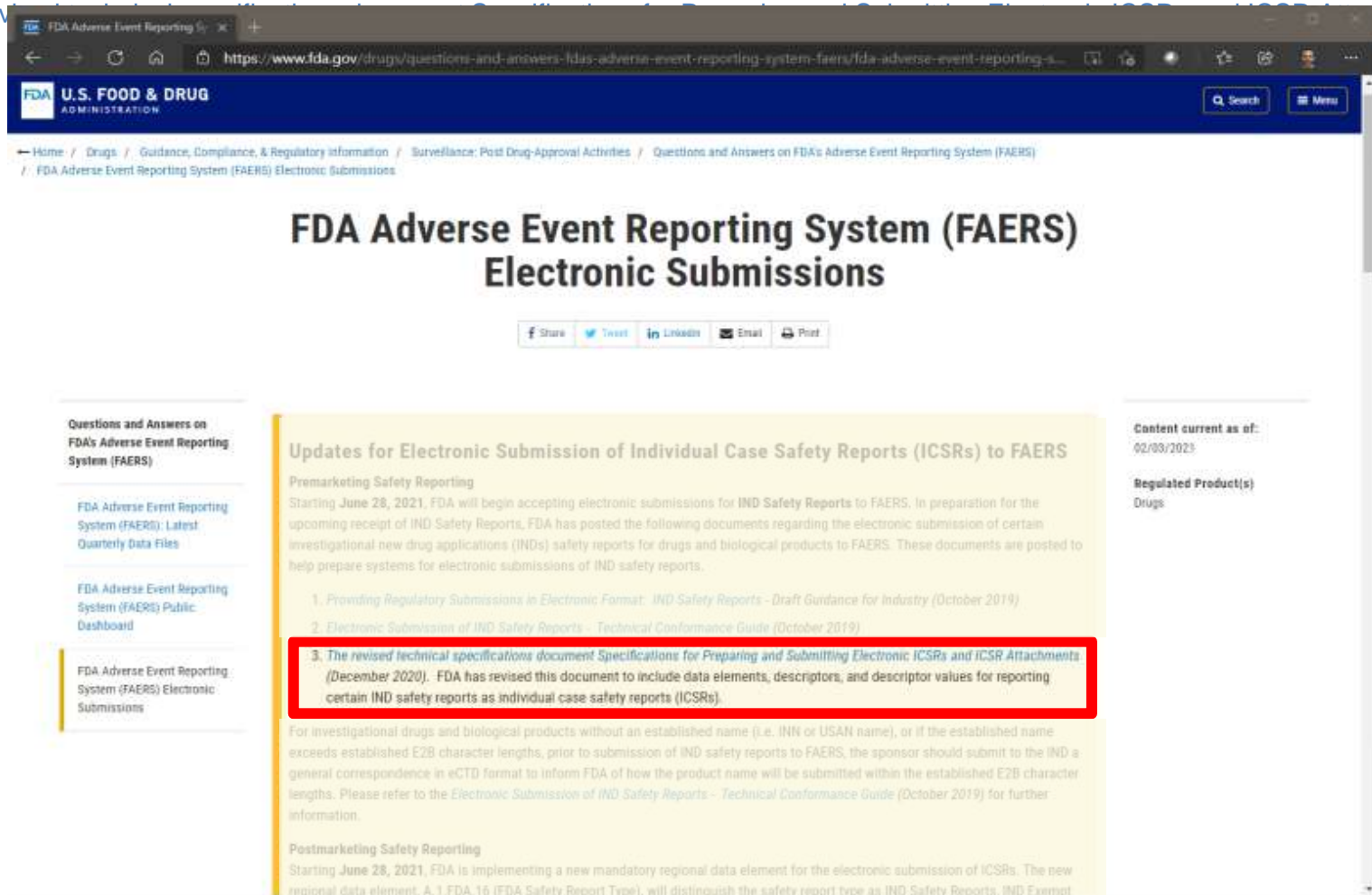
How does FDA use the information in FAERS?

FAERS is a useful tool for FDA for activities such as looking for new safety concerns that might be related to a marketed product, evaluating a manufacturer's compliance to reporting regulations and responding to outside requests for information. The reports in FAERS are evaluated by clinical reviewers, in the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER), to monitor the safety of products after they are approved by FDA.

Select

“3. The revised

Attachments”



U.S. FOOD & DRUG ADMINISTRATION

Home / Drugs / Guidance, Compliance, & Regulatory Information / Surveillance: Post Drug-Approval Activities / Questions and Answers on FDA's Adverse Event Reporting System (FAERS) / FDA Adverse Event Reporting System (FAERS) Electronic Submissions

FDA Adverse Event Reporting System (FAERS) Electronic Submissions

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Questions and Answers on FDA's Adverse Event Reporting System (FAERS)

- FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files
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Updates for Electronic Submission of Individual Case Safety Reports (ICSRs) to FAERS

Premarketing Safety Reporting

Starting June 28, 2021, FDA will begin accepting electronic submissions for IND Safety Reports to FAERS. In preparation for the upcoming receipt of IND Safety Reports, FDA has posted the following documents regarding the electronic submission of certain investigational new drug applications (INDs) safety reports for drugs and biological products to FAERS. These documents are posted to help prepare systems for electronic submissions of IND safety reports.

1. *Providing Regulatory Submissions in Electronic Format: IND Safety Reports - Draft Guidance for Industry (October 2019)*
2. *Electronic Submission of IND Safety Reports - Technical Conformance Guide (October 2019)*
3. **The revised technical specifications document Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments (December 2020). FDA has revised this document to include data elements, descriptors, and descriptor values for reporting certain IND safety reports as individual case safety reports (ICSRs).**

For investigational drugs and biological products without an established name (i.e. INN or USAN name), or if the established name exceeds established E2B character lengths, prior to submission of IND safety reports to FAERS, the sponsor should submit to the IND a general correspondence in eCTD format to inform FDA of how the product name will be submitted within the established E2B character lengths. Please refer to the *Electronic Submission of IND Safety Reports - Technical Conformance Guide (October 2019)* for further information.

Postmarketing Safety Reporting

Starting June 28, 2021, FDA is implementing a new mandatory regional data element for the electronic submission of ICSRs. The new regional data element, A.1.FDA.16 (FDA Safety Report Type), will distinguish the safety report type as IND Safety Reports, IND Exempt

Content current as of: 02/03/2023

Regulated Product(s)
Drugs

Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Technical Specifications Document

Associated Guidance Documents and Conformance Guide:

Draft Guidance for Industry: Providing Submissions in Electronic Format – Postmarketing Safety Reports (June 2014)

Guidance for Industry and FDA Staff: Postmarketing Safety Reporting for Combination Products (July 2019)

Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format: IND Safety Reports (September 2019)

Electronic Submissions of IND Safety Reports Technical Conformance Guide (September 2019)

For questions regarding this technical specifications document, contact the Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, Food and Drug Administration, at FAERSESUR@fda.hhs.gov; or Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, at CBERICSRSubmissions@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2020

2020-02-11	1.7	Added a new value to the data element B.4.k.1 for drug characterization to accommodate a similar device. Updated the data element B.4.k.18.2 to specify values. Updated the data element B.4.k.18.3 to use default values.
2020-12-18	1.8	Added a new regional data element A.1.FDA.16 (FDA Safety Report Type) in Table 2 Detailed Description of Administrative Tags Added section Submission Rules Added a new value to the data element B.4.k.1 and B.4.k.19 in section J Bioavailability/ Bioequivalence (BA/BE) Studies Not Conducted Under an IND

Table 2. Detailed Description of Administrative Tags¹

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
A.1.9	<fulfillexpeditecriteria>	1N	1= Yes (15-Day expedited) 2= No (non-expedited) 4= 5-Day 5= 30-Day 6= 7-Day 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
A.2.3.2 [‡]	<sponsorstudynumb>	35AN	IND or Pre-ANDA number under which the clinical trial where the event occurred is conducted
A.1.FDA.16 ^{††}	<fdasafetyreporttype>	1N	1=IND Safety Report 2=IND Exempt BA/BE Safety Report 3=Postmarketing Safety Report

¹Include either <companynumb> or <authoritynumb> values. FDA cannot process the US SR without one of these element values.

[†]The Sender's Safety Report Unique Identifier is comparable to the Manufacturer Report Number (also referred to as the Manufacturer Control Number (MCN)) provided on paper in FDA Form 3500A. This number is the company's unique case identification number, which is used for the life of the case.

[‡]For IND and IND-exempt BA/BE study safety reports only. An IND-exempt BA/BE study refers to a BA/BE study not conducted under IND.

^{††}The FDA Safety Report Type data element distinguishes premarket (IND and IND-Exempt BA/BE) safety reports from postmarketing safety reports and is used to determine which reports are posted publicly.

C. Authorization/ Application Number Format

In the section designated for drug and biological products information, use the following format for the "Authorization/ Application Number" element (B.4.k.4.1) <drugauthorizationnumb> as indicated in Table 3 and described below.

- For approved drug and biological products marketed under an approved application, include the acronym "NDA" or "ANDA," followed by a space and then the number for the application (e.g., NDA 012345, ANDA 012345). For prescription drug products marketed without an approved application (Rx No Application), use "000000." For a nonprescription drug product marketed without an approved application (Non-Rx No



Contact Information

FDA Adverse Event Reporting System (FAERS) Electronic Submissions



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For assistance contact the FAERS electronic submission coordinator at faeresub@fda.hhs.gov

Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

Technical Specifications Document

Associated Guidance Documents and Conformance Guide:

Draft Guidance for Industry: Providing Submissions in Electronic Format – Postmarketing Safety Reports (June 2014)

Guidance for Industry and FDA Staff: Postmarketing Safety Reporting for Combination Products (July 2019)

Draft Guidance for Industry: Providing Regulatory Submissions in Electronic Format: IND Safety Reports (September 2019)

Electronic Submissions of IND Safety Reports Technical Conformance Guide (September 2019)

For questions regarding this technical specifications document, contact the Office of Surveillance and Biometrics Research and Development, Center for Drug Evaluation and Research, Food and Drug Administration, at FAERESUB@fda.hhs.gov; Office of Communication, Outreach and Development, Center for Drug Evaluation and Research, Food and Drug Administration, at CDERICSRSUBmissions@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

December 2020

Technical Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments

<https://www.fda.gov/media/132096/download>

FAERS Electronic Submissions

<https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>

How to Request Safety Reporting Portal Account

1. Navigate to:
<https://www.safetyreporting.hhs.gov>
2. Click “Create Account”
3. Select “A manufacturer, investigator, sponsor or applicant of a drug or biologic product”
4. Select “Human Drug/Therapeutic Biologic (given to a human)”
<https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=9140736b-f914-4d10-8ee3-1ab02671f049>

FDA tool to test new requirements – Coming soon!

Date	Version	Summary of Changes
2020-12-18	1.8	<ul style="list-style-type: none"> Added a new regional data element A.1.FDA.16 (FDA Safety Report Type) in Table 2 Detailed Description of Administrative Tags Added section Submission Rules

Table 2. Detailed Description of Administrative Tags*

Element	DTD Descriptor 2.1	Length	Element Values for DTD 2.1
A.1.9	<fulfillexpeditecriteria>	1N	1= Yes (15-Day expedited) 2= No (non-expedited) 4= 5-Day 5= 30-Day 6= 7-Day expedited
A.1.0.1	<safetyreportid>	100AN	Sender's (Case) Safety Report Unique Identifier ¹
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
A.2.3.2 ²	<sponsorstudynumb>	35AN	IND or Pre-ANDA number under which the clinical trial where the event occurred is conducted
A.1.FDA.16³	<Idasafetyreporttype>	1N	1=IND Safety Report 2=IND Exempt BA/BI Safety Report 3=Postmarketing Safety Report



Continuing Education Questions

Challenge Question #1



What is the allowable value for the new data element FDA Safety Report Type for postmarket report?

- A. 1: IND Safety Report
- B. 2: IND Exempt BA/BE Safety Report
- C. 3: Postmarketing Safety Report
- D. None of the above

Challenge Question #2



Which condition will result in a negative acknowledgement of a FDA safety report?

A. `<fdasafetyreporttype>3</fdasafetyreporttype>`

AS2 Header where XML file: AERS or
Routing ID where XML file: FDA_AERS

B. `<fdasafetyreporttype>3</fdasafetyreporttype>`

AS2 Header where XML file: AERS_PREMKT or
Routing ID where XML file: FDA_AERS_PREMKT

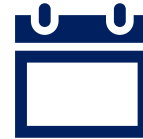
Key Takeaways



Create an account to use the Safety Reporting Portal (if applicable)



Select the most appropriate routing mechanism



Comply with new flag type requirement by June 28, 2021

Questions?

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