

ELECTRONIC SUBMISSION OF IND SAFETY REPORTS TECHNICAL CONFORMANCE GUIDE

This Document supplements the following Guidance Document:

Draft Guidance for Industry *Providing Regulatory Submissions in Electronic Format: IND Safety Reports* (October 2019)

For questions regarding this technical specifications document, contact CDER or CBER at faersesub@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)
Oncology Center of Excellence (OCE)**

April 2022



ELECTRONIC SUBMISSION OF IND SAFETY REPORTS TECHNICAL CONFORMANCE GUIDE

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REVISION HISTORY

DATE	VERSION	SUMMARY OF MAJOR REVISIONS
October 2019	1.0	Initial Version
April 2022	1.1	<ul style="list-style-type: none">• Added information regarding data elements needed for IND safety reports from aggregate analysis• Included provisions for submitting names of products without established names to the IND prior to electronic submissions to FAERS• Updated throughout to refer to IND safety reports submitted electronically to FAERS as IND ICSRs• Updated names of companion documents throughout

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Electronic Submission of IND Safety Reports Technical Conformance Guide¹

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1. Introduction

1.1 Background

This Technical Conformance Guide (Guide) provides specifications, recommendations, and general considerations on how to submit electronic investigational new drug application (IND) safety reports to the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). This Guide supplements the draft guidance for industry *Providing Regulatory Submissions in Electronic Format: IND Safety Reports* (October 2019),² which implements the electronic submission requirements of section 745A(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) with respect to electronic submissions for certain IND safety reports submitted to CDER or CBER.

1.2 Purpose

This Guide discusses the format for the submission of IND safety reports required under 21 CFR 312.32(c)(1)(i) as individual case safety reports (ICSRs) to the FDA Adverse Event Reporting System (FAERS) and provides recommendations to sponsors who elect to submit such ICSRs to FAERS before the requirement for submission to FAERS is in effect for applicable INDs.³ This Guide provides general information for sponsors of commercial and noncommercial INDs pertaining to electronic submission of IND safety reports and attachments in electronic format to

¹ This technical specifications document has been prepared by the Office of New Drugs in the Center for Drug Evaluation and Research, in cooperation with the Center for Biologics Evaluation and Research and the Oncology Center of Excellence, at the Food and Drug Administration. You may submit comments on this guidance at any time. Submit comments to Docket No. FDA-2018-D-1216 (available at <https://www.regulations.gov/docket?D=FDA-2018-D-1216>) (see the instructions for submitting comments in the docket).

² This guidance also provides information on the effective date of the requirement to provide certain regulatory submissions in electronic format. When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

³ FDA intends to post information on the FAERS Electronic Submissions web page (available at <https://www.fda.gov/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>) when the Agency will begin accepting electronic submission of IND ICSRs to FAERS.

FAERS. It also provides information to sponsors on the format for submission of IND safety reports required under section 312.32(c)(1) that should not be submitted to FAERS and should continue to be submitted in electronic common technical document (eCTD) format.⁴

1.3 Document Revision and Control

Sponsors will be able to access future revisions of this Guide through the FAERS Electronic Submissions web page,⁵ and the revision history page of this Guide will provide information on the changes made to previous versions.

1.4 Relationship to Other Documents

Sponsors should consult the following guidances and web pages for other aspects of electronic IND safety reporting:

- Draft guidance for industry *Providing Regulatory Submissions in Electronic Format: IND Safety Reports*⁶
- Technical specifications document *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products* (April 2022)⁷
- The FAERS Electronic Submissions web page for instructions on submission of ICSRs
- Guidance for industry *Providing Submissions in Electronic Format — Postmarketing Safety Reports* (April 2022) for instructions on contingency plans for submission of safety reports, for notification of receipt of submissions, and contingencies when the submissions systems are temporarily unavailable

⁴ See also the draft guidance for industry *Providing Regulatory Submissions in Electronic Format: IND Safety Reports*. When final, this guidance will represent the FDA's current thinking on this topic.

⁵ Available on the FAERS Electronic Submissions web page at <https://www.fda.gov/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>.

⁶ When final, this guidance will represent the FDA's current thinking on this topic.

⁷ Available on the FAERS Electronic Submissions web page at <https://www.fda.gov/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>.

2. General Considerations

2.1 IND Safety Report Submissions

2.1.1 ICSR and ICH E2B Data Standards

An ICSR is a description of an adverse drug event experienced by an individual subject. ICSRs are used to communicate information on clinical trial and postmarketing adverse drug events or adverse drug reactions between a variety of entities involved with the review and tracking of safety information (e.g., investigators, regulators, pharmaceutical companies, institutional review boards or ethics committees, reporters).

The International Council for Harmonisation (ICH) E2B data standards working group was created to provide common data elements for the electronic transmission of ICSRs globally between relevant stakeholders. FDA currently requires mandatory postmarketing safety reports to be submitted to FAERS⁸ and Vaccine Adverse Event Reporting System (VAERS) and certain IND safety reports will also be required to be submitted to FAERS when the requirement is in effect.⁹

2.1.2 IND Safety Reports

Certain IND safety report types required under 21 CFR 312.32(c)(1) contain individual data from one or more subjects and should be submitted as ICSRs to FAERS (hereafter, for the purposes of this document, these types of reports are referred to as IND ICSRs). Other types of required IND safety reports are reports of overall findings or pooled analyses from published and unpublished in vitro, animal, epidemiological, or clinical studies. The sponsor should submit these other types of reports in a narrative format in eCTD format and should *not* submit the reports to FAERS (see details in section 2.1.3 below).

2.1.3 IND Safety Reports That Should NOT Be Submitted to FAERS

IND safety reports that are not submitted to FAERS (see Table 1) are reports of overall findings or pooled analyses from published and unpublished in vitro, animal, epidemiological, or clinical studies and increased rate of occurrences of serious suspected adverse reactions. Reports of overall findings or pooled analyses as noted above are to be submitted in a narrative format (21 CFR 312.32(c)(1)(v)). These reports should be submitted in the following manner:

⁸ See the guidance for industry *Providing Submissions in Electronic Format — Postmarketing Safety Reports*.

⁹ For information on the effective date of the requirement, see the draft guidance for industry *Providing Regulatory Submissions in Electronic Format: IND Safety Reports*. When final, this guidance will represent the FDA's current thinking on this topic.

Contains Nonbinding Recommendations

- For INDs¹⁰ in eCTD format¹¹ using the following labels:
 - For findings from animal or in vitro testing (21 CFR 312.32(c)(1)(iii)): to the appropriate study using the “Safety Report” file-tag in eCTD section 4.2.3, Toxicology
 - For findings from other studies (21 CFR 312.32(c)(1)(ii)) and for an increased rate of occurrence of serious suspected adverse reactions (21 CFR 312.32(c)(1)(iv)): using the “Safety Report” file-tag in eCTD section 5.3.5.4, Other Safety Reports and Related Information

These IND safety reports in narrative format should not be submitted on MedWatch Form FDA 3500A or Council for International Organizations of Medical Sciences forms.

Table 1: Types of IND Safety Reports and Location of Submission

Type of report	Submit to FAERS*	Submit to eCTD*
A single occurrence of an adverse event that is uncommon and known to be strongly associated with drug exposure (21 CFR 312.32(c)(1)(i)(A))	X	
One or more occurrences of an adverse event that is not commonly associated with drug exposure, but is otherwise uncommon in the population exposed to the drug (21 CFR 312.32(c)(1)(i)(B))	X	
An aggregate analysis of specific adverse events observed in a clinical trial (e.g., known consequences of the underlying disease or condition under investigation, other events that commonly occur in the study population independent of drug therapy) that indicates those events occur more frequently in the drug treatment group than in a concurrent or historical control group (21 CFR 312.32(c)(1)(i)(C))	X	
Findings from other studies (21 CFR 312.32(c)(1)(ii))		X
Findings from animal or in vitro testing (21 CFR 312.32(c)(1)(iii))		X
Increased rate of occurrence of serious suspected adverse events (21 CFR 312.32(c)(1)(iv))		X

¹⁰ For a safety report submitted to a noncommercial IND that is not in eCTD format, see the guidance for industry *Providing Regulatory Submissions in Alternate Electronic Format* (July 2021).

¹¹ See guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using eCTD Specifications* (February 2020).

* FAERS = FDA Adverse Event Reporting System; eCTD = electronic common technical document.

2.1.4 Transition to Submitting IND ICSRs to FAERS

FDA will accept IND ICSRs to FAERS as part of a voluntary submission program prior to the time that the requirement is in effect for applicable INDs.¹²

If sponsors choose to participate in the voluntary submission program, they should submit all IND ICSRs to FAERS and should not switch back to submission in eCTD format. This will allow for initial and follow-up reports and reports for cross-reported INDs to reside in the same system from a given timepoint forward.

2.1.5 IND ICSR Attachments

Attachments to IND ICSRs include supporting information, such as autopsy reports, or published articles for IND ICSRs based on scientific literature. Attachments can also be used for narrative portions of the IND ICSR that exceed character limitation for that E2B data field; however, FDA encourages sponsors to construct informative narratives that fit within the character limitations.

2.1.6 Follow-Up Reports

A follow-up report includes new information about an adverse drug reaction that has been previously reported in an initial IND ICSR, and all follow-up reports should use the same unique case identification number as the initial IND ICSR. Follow-up IND ICSRs should include all information in the structured fields of the IND ICSR that has been previously reported along with any new information. However, to avoid duplication, IND ICSR attachments such as scientific literature or autopsy reports submitted with an initial IND ICSR should not be resubmitted with a follow-up IND ICSR.

2.1.7 Identification of the IND for Submissions of IND ICSRs

As discussed in the guidance for industry and investigators *Safety Reporting Requirements for INDs and BA/BE Studies* (December 2012), IND safety reports should be submitted to all of the sponsor's INDs under which the drug is being administered. To submit IND safety reports to all relevant INDs electronically to FAERS, the sponsor should create one IND ICSR using the appropriate E2B data elements as described below.

For an IND ICSR to be successfully processed in FAERS, it needs to have one valid IND number in the appropriate E2B data field. Sponsors should use the IND number under which the clinical trial where the event occurs is conducted as the *primary IND* number in the indicated E2B data field. Sponsors should also use the indicated repeatable E2B data field to list individually other relevant INDs for which notification is necessary (i.e., *cross-reporting*) as described in the guidance for industry and investigators *Safety Reporting Requirements for INDs*

¹² Additional information on the voluntary submission process is available on the FAERS Electronic Submissions web page at <https://www.fda.gov/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>.

and BA/BE Studies and the draft guidance for industry *Sponsor Responsibilities — Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies* (June 2021).¹³ The relevant FDA review staff for each IND identified in the FAERS report will be notified that an IND ICSR has been submitted for that drug.

Sponsors should see the technical specifications document referenced in this Guide, *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products*, for information on E2B data elements to populate with the appropriate IND numbers as discussed above.

2.1.7.1 IND ICSRs From an Aggregate Analysis

IND ICSRs that are a result of an aggregate analysis (21 CFR 312.32(c)(1)(i)(C)) of clinical trials that are conducted under multiple INDs should be submitted to the *parent IND* using electronic reporting to FAERS. The *parent IND* is the IND under which clinical trials were first initiated in the United States. If the drug is being evaluated in multiple INDs, the parent IND is generally the IND with the lowest number.

As discussed in the guidance for industry and investigators *Safety Reporting Requirements for INDs and BA/BE Studies*, IND safety reports that are a result of an aggregate analysis should include a narrative report (hereafter referred to as a *narrative summary report*) that provides a summary of the cases and the analysis the sponsor conducted and should identify the individual cases that contributed to the analysis. The sponsor should submit one IND ICSR to FAERS that includes the following minimum information listed by E2B data element name with additional clarifying information in parentheses:

- Sender’s (case) Safety Report Unique Identifier
 - Type of Report (should = “Report from study”)
 - Date of Most Recent Information for This Report
 - Information on Sender of Case Safety Report (type, name, address, etc.)
 - Local Criteria Report Type (15- or 7-day report)
 - MedDRA Version for Reaction/Event¹⁴
 - Reaction/Event (MedDRA code)
 - Seriousness Criteria at Event Level (list most common criteria among all of the individual cases)
 - Characterisation of Drug Role
 - Substance/Specified Substance Name
 - Source of Assessment
 - Result of Assessment
- The term *aggregate* in the E2B field “Patient” to indicate that the report is a report from an aggregate analysis

¹³ When final, this guidance will represent the FDA’s current thinking on this topic.

¹⁴ MedDRA is an acronym for Medical Dictionary for Regulatory Activities.

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- The unique case identification number of each IND ICSR that contributed to the analysis, listed in the appropriate E2B field as a linked report. If individual cases that contributed to the analysis were previously submitted as IND safety reports in eCTD format, the sponsor should list the eCTD sequence number¹⁵ and date of submission along with the unique case identification number/manufacture control number in the narrative summary report that is attached to the IND ICSR as a PDF.
- The narrative summary report attached to the IND ICSR as a PDF and clearly titled “Narrative summary report for an IND safety report from an aggregate analysis_IND number_product_date of report.”

Sponsors should reference the technical specifications document *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products* for instructions on the appropriate data elements to include in IND ICSRs from aggregate analyses as per 21 CFR 312.32(c)(1)(i)(C), on how to link all supportive IND ICSRs to the report, and on where to include the narrative summary report. This information may also be applicable for IND ICSRs submitted as per 21 CFR 312.32(c)(1)(i)(B) that include more than one case and where a narrative summary report is provided.

2.1.8 Product Names for Investigational Drugs

Sponsors should use the established name (generally the United States Adopted Name or international nonproprietary name), if applicable, in the appropriate E2B product field for investigational drugs. For investigational drugs without an established name, or if the established name or the name of the active ingredient(s) in the product exceeds established E2B character lengths, before submission of IND ICSRs to FAERS, the sponsor should submit to the IND a general correspondence in eCTD format containing the full name of the medicinal product, product name to be used for E2B reporting (FDA recommends company code, if available), full name of the active ingredient(s), and active ingredient(s) name to be used for E2B reporting as in Table 2 below.

¹⁵ The eCTD sequence number is the unique four-digit number for each IND submission the sponsor submits in the us-regional.xml file for the eCTD submission.

Table 2: Information to Include in “General Correspondence – Product E2B File”*

IND number	Full name of medicinal product	Product name to be used for E2B reporting (FDA recommends company code, if available)	Full name of the active ingredient(s). Separate multiple ingredients with a backslash character (\)	Active ingredient(s) name to be used for E2B reporting

*IND = investigational new drug application; E2B = International Council for Harmonisation E2B data standards.

The document should be placed in “1.2 Cover letters,” and sponsors should clearly identify the submission as “General Correspondence – Product E2B File”.

2.1.9 Safety Reports for Marketed Drugs

For an adverse event associated with a marketed drug evaluated under an IND that meets IND *and* postmarketing safety reporting requirements (21 CFR 312.32(c)(1)(i) *and* 314.80, 600.80, or 310.305), the sponsor should submit two separate ICSRs to FAERS: one ICSR referencing the new drug application (NDA) or biologics license application (BLA) in the “Authorization/Application Number” field and one IND ICSR referencing the IND as described under section 2.1.7., Identification of the IND for Submissions of IND ICSRs.

For adverse events that occur with a marketed vaccine evaluated under an IND that meet IND *and* postmarketing safety reporting requirements (21 CFR 312.32(c)(1)(i) *and* 600.80), the sponsor should submit two separate ICSRs: one to VAERS for the BLA and one IND ICSR to FAERS for the IND.

2.1.10 Other Considerations

Sponsors should reference the technical specifications document *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products* and the FAERS Electronic Submissions web page for the following information:

- Required E2B data elements for IND ICSRs
- Regional specifications of the E2B data elements
- Use of E2B data elements for a variety of reporting scenarios

- Submission of a narrative summary report as per 21 CFR 312.32(c)(1)(i)(C) or for several reports submitted as per 21 CFR 312.32(c)(1)(i)(B)) and linking the unique case identification numbers of the IND ICSRs supporting the narrative summary report

2.1.11 Options For Electronic Submission of IND ICSRs: Electronic Submissions Gateway or Safety Reporting Portal

IND ICSRs (initial and follow-up reports and all attachments) for drugs addressed by this Guide are submitted as IND ICSRs to the FAERS database.¹⁶ FDA provides two options for electronic submission of IND ICSRs and attachments to FAERS: (1) direct submission through the Electronic Submissions Gateway (ESG) or (2) submission through the Safety Reporting Portal (SRP), both of which are available 24 hours a day, 7 days a week.

Direct submission of IND ICSRs through the ESG is described on the FAERS Electronic Submissions web page. This option involves direct transmission of IND ICSRs from a firm's database to FDA through the ESG. The ESG is a central transmission point for sending information electronically to FDA. Once received through the ESG, the submitted reports are processed into the FAERS database. For instructions on organizing, preparing, and submitting IND ICSRs and attachments using the direct submission method through the ESG, see the technical specifications document *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products*. The technical specifications document addresses topics such as data elements, electronic transport format, and types of IND ICSR attachments FDA currently accepts.

The submission of IND ICSRs and IND ICSR attachments through the SRP is described on the FDA's SRP web page.¹⁷ Users enter the IND ICSR information manually into a web-based form, and this information is then submitted to FDA to be uploaded into the FAERS database.

2.1.11.1 Separate Submission Pathway for Submitting IND ICSRs to FAERS

FDA established a separate submission pathway within the ESG and SRP for submitting IND ICSRs to FAERS to keep premarket and postmarketing reports separate in the FAERS database. In addition, FDA created a new FDA region-specific data element to distinguish premarket and postmarketing safety reports. Certain postmarketing data are periodically posted on the public FAERS dashboard, and reports submitted through the premarket pathway will not be posted to the public dashboard. . If an adverse event met both IND and postmarketing safety reporting requirements the ICSR submitted to the postmarketing pathway will be subject to posting on the FAERS public dashboard.

FDA has implemented business rules to identify IND ICSRs that are incorrectly submitted to the postmarketing pathway in FAERS. Files submitted to the postmarketing pathway in FAERS

¹⁶ See the Questions and Answers on FAERS web page at <https://www.fda.gov/drugs/surveillance/fda-adverse-event-reporting-system-faers>.

¹⁷ Available at <https://www.safetyreporting.hhs.gov/SRP2/en/Home.aspx?sid=0183c2c0-8952-49cb-81f1-0c3d37baa819>.

with certain criteria will be rejected and sponsors will receive a negative acknowledgement with the reason for the rejection.¹⁸

2.1.11.2 Creating an Account Before the First Electronic Submission

To submit IND ICSRs electronically, either through the ESG or SRP, the sponsor needs to have an account with FDA. To create an account, the sponsor should contact the FAERS electronic submissions coordinator at faersesub@fda.hhs.gov. The FAERS electronic submissions coordinator will assist sponsors to ensure that all steps have been completed for successful submission of IND ICSRs and attachments.

2.1.11.3 Unique Case Identification Numbers for IND Safety Reports

Each IND ICSR should have a unique case identification number. The sponsor should use the same unique case identification number for an initial IND ICSR and any of its follow-up reports so that the reports can be associated with an individual case. Case identification numbers are assigned based on one of the three methods of submission described below:

- a. **Via the SRP:** The unique case identification number for an initial report is automatically generated by the SRP once the IND ICSR is submitted.
- b. **Via the ESG:** The unique case identification number for an initial report is generated by the sponsor before submitting the report.
- c. **On Paper** (e.g., MedWatch Form FDA 3500A):¹⁹ The unique case identification number is the manufacturer control number that the sponsor assigns for the initial report.

The sponsor should use the same unique case identification number for an initial IND ICSR and its follow-up reports even if there is a transfer of ownership of an application. If the current sponsor submits a follow-up IND ICSR to an initial report submitted by a previous sponsor, the current sponsor should use the unique case identification number from the initial IND ICSR to ensure that the follow-up report can be matched with the initial submission.

Similarly, if the sponsor submits an initial IND ICSR through the ESG, the sponsor *cannot* submit the follow-up reports for this case through the SRP because the initial and follow-up reports will have different unique case identification numbers.

¹⁸ For additional details on rejection criteria for IND safety reports, see the FDA E2B(R3) Core and Regional Data Elements and Business Rules document available on the FAERS Electronic Submissions web page at <https://www.fda.gov/drugs/fda-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions>.

¹⁹ Sponsors who submit a follow-up report to FAERS for an earlier report that was submitted on paper or in eCTD format should use the same manufacturer control number for the initial and all follow-up reports.

2.1.11.4 Single Submission Versus Batched Submission of IND ICSRs

When submitting IND ICSRs through the ESG, the sponsor can submit the reports either as a single report or as several reports in a batch. See the technical specifications document *FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products* for information on submitting a single IND ICSR versus a batch of IND ICSRs through the ESG.

If the sponsor is submitting IND ICSRs through the SRP, the sponsor can only submit a single IND ICSR at a time because the SRP is not able to process a batched submission.

2.1.12 Notification of Receipt of Submissions by the FDA

For information on the notification of FDA's receipt of a submission, see the guidance for industry *Providing Submissions in Electronic Format — Postmarketing Safety Reports* and the FAERS Electronic Submissions web page.