Case Scenario 2

Report from aggregate analysis as per 312.32(c)(1)(i)(C) or 312.32(c)(1)(i)(B)

Data Element	DTD Descriptor 2.1	Title	Element values (notes)
A.1.12	<linkedreportnumber>	Identification number of reports linked to this report	(Used to link all individual cases (safetyreportid) that make up an IND Safety Report submitted as a result of an Aggregate Analysis)
A.2.3.2	<sponsorstudynumb>	Sponsor Study Number	(Use the “parent” IND number)
A.2.3.3	<observestudytype>	Study Type	1 = clinical trials 2 = individual patient use 3 = other studies 4 = Report from aggregate analysis
B.1.1	<patientinitial>	Patient identifier	Aggregate

Case Scenarios

- See additional information and other case scenarios in appendix of *Specifications for Preparing and Submitting Electronic ICSRs and ICSR Attachments*

Challenge Question #1

Which of the following are required elements for submission of IND safety reports to FAERS?

A. Suspect product
B. IND number
C. Form 1571
D. Both A and B

Challenge Question #2

True or False: FDA is currently accepting IND safety reports to FAERS.

A. True

B. False

Challenge Question #3

What types of IND safety reports will not be submitted to FAERS?

A. A single occurrence of an event that is uncommon and known to be strongly associated with drug exposure (21 CFR 312.32(c)(1)(i)(A)

B. One or more occurrences of an 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)

C. An aggregate analysis of specific events observed in a clinical trial (known consequences of the underlying disease or condition) 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)

D. Findings from animal or in vitro testing (21 CFR 312.32(c)(1)(iii))

Submit Your Questions

and we will get to them after we hear from

Suranjan De

Routing Mechanism

Setting up routing controls dictating where a document is sent

- Two options :
  - Add the custom header attributes to the header of the message to indicate the type of submission (e.g. an IND) and destination (e.g. CDER). Reference ***Appendix F., AS2 Header Attributes***, for information on header attributes content and format.

OR

  - Use a unique routing ID to identify the types of submissions and destination. The selection of the routing ID can be automated in the Cyclone/Axway products through the back-end integration pick-up as described in ***Appendix J., AS2 Routing IDs***.

Routing Mechanism

Trading Partner Changes

- **AS2 <u>Header Attributes</u>**

  - For current post market reports
    - Destination: “CDER”
    - Attribute values: “**AERS**” for XMLs and “**AERS_ATTACHMENTS**” for PDFs

  - For IND safety reports, new header attributes need to be configured to route the files into the new folders.
    - Destination remains the same
    - Attribute values: “**AERS_PREMKT**” for XMLs and “**AERS_ATTACHMENTS_PREMKT**” for PDFs

Routing Mechanism

Trading Partner Changes

- **AS2 <u>Routing IDs</u>** - ESG also provides alternate method to submit the files using unique routing IDs

  – For current post market reports
    - Routing IDs: "**FDA_AERS**" for XMLs and "**FDA_AERS_ATTACHMENTS**" for PDFs

  – For IND safety reports, new Routing IDs need to be setup and corresponding configuration changes are required
    - Routing IDs: "**FDA_AERS_PREMKT**" for XMLs and "**FDA_AERS_ATTACHMENTS_PREMKT**" for PDFs

Triage of ICSRs

Sponsor Submission

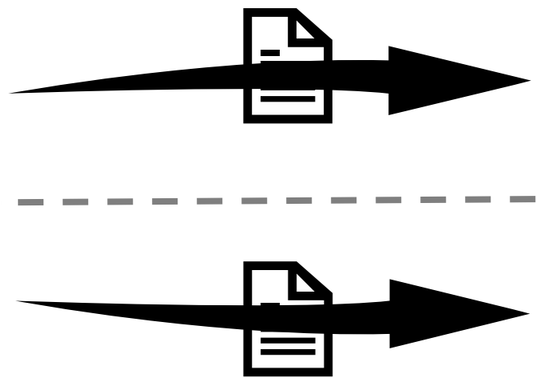
FDA Adverse Event Reporting System

Pre-Market ICSR Submission

AS2* Header: AERS_PREMKT or
AS2 Routing ID: FDA_AERS_PREMKT

A.1.01: Sender's Report ID
A.1.4: 2
A.2.3.1: eCTD STF Name
A.2.3.2: **IND number (Mandatory)**
A.2.3.3: accordingly
…

A.1.01: Sender's Report ID + "-IND"
…
…
…



Post-Market ICSR Submission

AS2 Header: AERS or
AS2 Routing ID: FDA_AERS

A.1.01: Sender's Report ID
A.1.4: 1
A.2.3.1: empty
A.2.3.2: empty
A.2.3.3: empty
B.4.k.4.1: NDA 07852
…

A.1.01: Sender's Report ID (stay as is)
…
…
…

*AS2: System-to-System. FDA ESG support two methods of communication: WebTrader and AS2 (System-to-System). WebTrader for small, simple, light submissions; AS2 for large, frequent submissions.

Summary

- FDA draft guidance and technical specification documents recently published regarding submission of IND safety reports to FAERS
- **<u>FDA is NOT currently accepting IND safety reports to FAERS</u>**
  - FDA will announce when the voluntary submission process will begin
- Requirement will be in effect 2 years after the final guidance
- IND-specific E2B data elements are <u>critical</u> to ensure regulatory requirements are met

We will take a short break to review your questions and will be right back with answers