FDA Adverse Event Reporting System (FAERS) Electronic Submissions – E2B(R3) Standards

Preparing for the electronic exchange of safety reports

Organizations should perform testing in the FAERS pre-production environment before they can initiate the electronic transmission with the FAERS production environment. This is to ensure that their local safety/pharmacovigilance database can successfully transmit ICSRs in electronic format to the FAERS database and be compliant with messaging format, terminology, and regional requirements.

Type of Organization

Testing applies to organizations that electronically report ICSRs to FAERS for the first time ("new organizations") or organizations that introduce a major change to their local safety/pharmacovigilance database which might impact the electronic reporting of ICSRs ("major changes").

In addition, FDA supports initial testing of software/system solutions by IT vendors and third-party service providers ("third-party service providers").

Below is an overview of the steps users should follow for the electronic transmission of ICSRs depending on their type of organization and technical infrastructure:

Type of Organization	Steps
New organization using a gateway and a local safety/pharmacovigilance database • Industry • Sponsors of clinical trials	Complete steps 1 - 4 (see FAERS testing steps below)
Major change (gateway and/or a local safety/pharmacovigilance database) • Industry • Sponsors of clinical trials	Complete steps 2, 3 and 4 (see FAERS testing steps below)
Third-party service providers and IT tool vendors	Complete steps 1 - 4 (see FAERS testing steps below)

FAERS testing steps

Step 1: Register with the FDA's Electronic Submission Gateway (ESG)

To complete the registration of a new organization for the submission of ICSRs, follow the steps described on the *Create an ESG Account web page*. Follow the checklist to establish a WebTrader or AS2 (System-to-System) account as appropriate for your organization.

Step 2: Development and validation testing using FDA E2B(R3) Validator

Gateway partners should carry out development activities based on the technical specifications documents published by both ICH and FDA, and validate the E2B(R3) XML test files generated from their safety database using FDA E2B(R3) Validator. If no errors occur, please move to the next step. If the

E2B(R3) Validator identifies any error(s), please correct the error(s) in your safety database and verify the test file submission generates no errors upon resubmission before moving to the next step.

Step 3: XML test phase

Send sample test ICSRs, as XML files, with the appropriate AS2 Header or Routing ID, batch receiver identifier and message receiver identifier specified in the *Technical Specifications Document - FDA Regional Implementation Guide for E2B(R3) Electronic Transmission of Individual Case Safety Reports for Drug and Biological Products* to the ESG test environment. *Note: Use the test ESG accounts, AS2 Header or Routing ID and the test values for batch receiver identifier.*

FDA will ensure the XML files are accurate and comply with the required specifications: syntax, field lengths, minimum information, data coding against the applicable standard terminology and business rules as defined in the document *FDA E2B(R3) Core and Regional Data Elements and Business Rules*. Also follow the xPaths for all the data elements to avoid loss of data, especially on the optional data elements.

Step 4: Production

Once all tests are successfully completed and two positive acknowledgements were received for each test ICSR, organizations may begin to submit ICSRs electronically to the FAERS database. Please verify that WebTrader or AS2 production accounts have been established, as appropriate, for your organization before sending production XML files.

Organizations must communicate major technical changes immediately to FDA by contacting FAERS electronic submission coordinator at faersesub@fda.hhs.gov. Major technical changes may require re-testing as described above.