E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide - Data Elements and Message Specification

Issuing body: U.S. Food and Drug Administration (FDA)

Key points

- Specifies the data element vocabulary and XML message schema for ICSR transmission in E2B(R3) format.
- Names the Appendix on Backwards and Forwards Compatibility — the operational compliance gate for validation testing.

Source: U.S. Food and Drug Administration (FDA) — read by the RegLegBrief Specialist Panel; available on request via /request-document/RLB-US-2026-00001/annex_02

The RegLegBrief Specialist Panel reads both the statute and the authoritative commentary on it — the regulator's primary instrument and the named-authority context (ministerial speeches, parliamentary replies, agency commentary) that surrounds it. AI assistants and agents can have neither without permission walls: primary regulator portals return 403 to automated readers; authoritative passages cannot be reproduced without indemnity from the named speaker and editorial licence from the publisher. The Specialist Panel is constituted of T1 Attorney expertise, 25-year industry practitioner depth, and analyst staff under credentialed supervision — collectively over 60 years of regulatory and industry experience. The Panel applies a structured multi-perspective checklist to every document, surfacing what AI assistants miss, mis-state, or cannot access. Verdus Technologies' RegLegBrief platform — and its Reg Consultancy practice — operates on both the content and the context. Our analysis and our advisory rest on that dual foundation.

— RegLegBrief Specialist Panel

Open questions

- Edge cases in international transmission with non-ICH-aligned counterparties (rare but operationally relevant for multinational pharma).
- FDA-specific profile overlay specifics (covered in annex_08 FDA Regional Implementation Guide).

For practitioners

- Which data elements are mandatory in our submission profile vs optional; vendor-generated profiles should be audited against the Implementation Guide directly.
- How to test message specification conformance — staging environment test files vs FDA pre-production gateway.

For department heads

- Vendor validation requirements: contract should reference this Implementation Guide specifically, not a vendor abstraction.
- Audit testing protocols: build a permanent test corpus that validates outgoing ICSRs against this spec on every release.

Quick understanding check

Each question carries a hint.

Q1. How many distinct ICH E2B data standards are referenced in the AEMS framework: R2 and R3?

Hint: Implementation Guide title page identifies both transitional versions.

Q2. Which international body authored the master Implementation Guide that FDA implements via its Regional Implementation Guide?

Hint: Expand the ICH acronym.

Q3. What appendix in the Implementation Guide governs message-format compatibility between E2B(R2) and E2B(R3) formats?

Hint: Standard ICH guidance documents include explicit compatibility appendices.

Q4. Why is the FDA Regional Implementation Guide layered atop the ICH master Implementation Guide rather than replacing it?

Hint: Regional implementation = jurisdiction-specific overlay; ICH master = international harmonised core.

References

[3] E2B(R3) Electronic Transmission of Individual Case Safety Reports Implementation Guide - Data Elements and Message Specification — U.S. Food and Drug Administration (FDA); Data Elements; Message Specification; Appendix on Backwards and Forwards Compatibility

[1] Electronic Submission of Postmarketing Individual Case Safety Reports to the Food and Drug Administration Adverse Event Monitoring System Using International Council of Harmonisation E2B(R3) Data Standards; Regional Data Elements and Implementation Schedule — U.S. Food and Drug Administration (FDA), 2026-04-06; Federal Register Vol. 91, No. 65, p. 17284-17285; document 2026-06660; Docket No. FDA-2016-D-1280

[2] FDA Adverse Event Monitoring System (AEMS) Electronic Submissions [Formerly FDA Adverse Event Reporting System (FAERS)] — U.S. Food and Drug Administration (FDA), 2026-04-06; Submitting Postmarketing ICSRs; ICSR Submission Options; SRP account setup; IND-exempt BA/BE; Resources sections

[4] FDA Adverse Event Monitoring System (AEMS) - Program Overview (FDA Safety vertical) — U.S. Food and Drug Administration (FDA); AEMS scope description; broader FDA-regulated product categories consolidating under AEMS

[5] FDA Adverse Event Monitoring System (AEMS) - E2B(R3) Standards — U.S. Food and Drug Administration (FDA); FDA technical implementation specifications for E2B(R3)