

# FDA Adverse Event Monitoring System (AEMS) - E2B(R3) Standards

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

## Key points

- Documents FDA's specific E2B(R3) technical implementation profile and the validation gates FDA enforces at intake.

**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\\_04](#)

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— RegLegBrief Specialist Panel

## Open questions

- How FDA's profile diverges from the ICH master specification in edge cases (typically minor but practitioner-meaningful at scale).

## For practitioners

- Which FDA-specific validation tests apply to our submissions and how to integrate them into pre-submission staging.

## For department heads

- Tooling vendor selection: ensure the vendor profile matches FDA's profile, not a generic ICH-only profile.

## Quick understanding check

*Each question carries a hint.*

**Q1.** How many vertical-specific AEMS standards pages does FDA's Drugs vertical maintain (one for each transitional data standard: R3 and R2)?

*Hint: FDA's AEMS Drugs vertical has both R3 and R2 Standards pages.*

**Q2.** Whose specific E2B(R3) implementation profile does this page describe — the international standard or FDA's regional layer?

*Hint: Page title says FDA AEMS E2B(R3) Standards.*

**Q3.** What is the relationship between FDA's E2B(R3) implementation profile (this page) and the ICH master Implementation Guide (annex\_02)?

*Hint: FDA layers regional fields atop the international standard.*

**Q4.** If a sponsor's submission vendor profile aligns with ICH master but not FDA Regional, what is the operational risk at AEMS intake?

*Hint: FDA validates regional-specific fields and rules at submission.*

## References

- <sup>5</sup> FDA Adverse Event Monitoring System (AEMS) - E2B(R3) Standards — U.S. Food and Drug Administration (FDA); FDA technical implementation specifications for E2B(R3)
- <sup>1</sup> 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
- <sup>2</sup> 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
- <sup>3</sup> 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
- <sup>4</sup> 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