FDA Adverse Event Monitoring System (AEMS) Electronic Submissions - E2B(R2) Standards

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

Key points

- Documents the transitional E2B(R2) acceptance window through 30 September 2026.
- Names the sunset condition: from 1 October 2026 R2 is no longer accepted by FDA AEMS 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_05

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— RegLegBrief Specialist Panel

Open questions

• Cutover planning for sponsors still on R2 close to the deadline — particularly small biotechs with limited validation bandwidth.

For practitioners

• When to retire R2 production capability vs maintaining parallel R2/R3 generation through the transition window.

• Whether to send the final R2 batch a week or two before the deadline to avoid last-day risk.

For department heads

• Risk assessment for delayed cutover: what is the contingency plan if our validated R3 pipeline fails its first production run in early October 2026?

Quick understanding check

Each question carries a hint.

Q1. Through what date will FDA AEMS continue to accept E2B(R2)-formatted postmarketing ICSRs? Answer in DD Month YYYY or YYYY-MM-DD format.

Hint: Sunset date for E2B(R2) acceptance.

Q2. Which FDA AEMS standards page describes the transitional R2 format, versus the parallel R3 standards page?

Hint: URL path includes 'e2br2-standards'.

Q3. What happens to E2B(R2)-formatted ICSR submissions after 30 September 2026?

Hint: Acceptance window ends; mandatory cutover.

Q4. What is the operational risk of submitting an R2 batch close to the 30 September 2026 deadline if production R3 pipeline has not yet been validated?

Hint: Risk: validation failure during the no-R2-fallback window.

References

[6] FDA Adverse Event Monitoring System (AEMS) Electronic Submissions - E2B(R2) Standards — U.S. Food and Drug Administration (FDA); Transitional E2B(R2) format requirements; sunset date 30 September 2026

[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

[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

[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