

# Change management for the EudraVigilance system

Issuing body: European Medicines Agency (EMA) — Date: 2022-06-30

## Key points

- Documents the EU operational model — ICH E2B(R3) mandatory since 30 June 2022; E2B(R2) no longer accepted at all.
- Provides the international comparator that places FDA's October 2026 date in catch-up alignment, not vanguard.

**Source:** European Medicines Agency (EMA) — read by the RegLegBrief Specialist Panel; available on request via [/request-document/RLB-US-2026-00001/annex\\_07](#)

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## Open questions

- EU-US data-exchange synchronisation between FDA AEMS and EMA EudraVigilance for multinational sponsors.
- Specific divergences between FDA Regional Implementation Guide and EMA implementation that affect cross-jurisdictional case reporting.

## For practitioners

- How our multinational case reporting workflow operates across both gateways during and after the transition window.
- Whether our internal R3 profile is closer to FDA-specific or EMA-specific — and what the cost of mis-alignment is.

## For department heads

- Global pharmacovigilance enterprise architecture: post-October-2026 the two largest pharmacovigilance gateways are both on the same ICH E2B(R3) base — opportunity to consolidate enterprise tooling around a single profile with regional overlays.

## Quick understanding check

Each question carries a hint.

**Q1.** EMA EudraVigilance mandated ICH E2B(R3) since 30 June 2022. FDA's mandatory date is 1 October 2026. Approximately how many years separate the two mandates?

*Hint: From mid-2022 to late-2026 is about.*

**Q2.** Which European regulator manages the EudraVigilance pharmacovigilance database?

*Hint: EMA acronym - European Medicines Agency.*

**Q3.** Does EMA EudraVigilance still accept E2B(R2) format today?

*Hint: Operational state since 30 June 2022.*

**Q4.** For a multinational sponsor operating in both EU and US, what is the practical implication of FDA's alignment with EMA's already-operational E2B(R3) standard post-October-2026?

*Hint: Same R3 messages can flow to both regulators with regional overlays.*

## References

<sup>8</sup> Change management for the EudraVigilance system — European Medicines Agency (EMA), 2022-06-30; EU mandatory ICH E2B(R3) since 30 June 2022; EudraVigilance no longer accepts E2B(R2)

<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