

ICH E2B(R3) Readiness Checklist

For IND Sponsors and Small Biotech Pharmacovigilance Teams

Mandatory deadline: April 1, 2026 | FDA FAERS E2B(R3) Electronic ICSR Submission

Use this checklist to assess your organization's readiness for mandatory ICH E2B(R3) ICSR electronic submissions to the FDA. Each item maps directly to a compliance requirement under 21 CFR 312.32, the FDA's April 2024 final guidance, or sound pharmacovigilance practice.

1 SUBMISSION INFRASTRUCTURE

- FDA Electronic Submissions Gateway (ESG) account created**
Required for database-to-database E2B(R3) transmission to FAERS
- WebTrader account configured and tested with FDA**
Separate from ESG; required for IND premarket ICSR submissions
- E2B(R3) XML generation capability confirmed**
Via safety database, validated software platform, or qualified CRO
- Test submissions completed in FDA FAERS staging environment**
Use the FDA validator at faers2-validator.preprod.fda.gov
- E2B(R3) forward-compatible rules reviewed**
FDA published forward-compatible rules April 2022; validate against current version
- If using a CRO: written confirmation of E2B(R3) readiness obtained**
CROs must independently confirm ESG connectivity and XML validation capability

2 ADVERSE EVENT INTAKE

- Structured AE intake form captures all minimum E2B(R3) data elements**
Reporter info, patient demographics, event details, product info, seriousness criteria
- Reporter qualification captured at first receipt**
HCP, consumer, patient, or other; materially affects ICSR validity
- MedDRA-aligned event description captured at intake**
Reduces coding effort and inconsistency downstream

- Seriousness criteria assessed and documented at intake
Death, life-threatening, hospitalization, disability, congenital anomaly, other medically important
- Expectedness assessment against current Investigator Brochure documented
Required for determining 7-day vs. 15-day reporting timeline under 21 CFR 312.32
- Multi-channel intake supported
Phone, email, site fax, web form; all routes captured in single system of record
- Clock-start date documented for every case
Day 0 = date of first receipt of minimum criteria for a valid ICSR

3 CASE MANAGEMENT AND WORKFLOW

- Case management system is validated under GAMP 5 and 21 CFR Part 11
Required for GxP-compliant electronic records and audit trail
- 7-day and 15-day reporting timelines tracked and enforced in system
7-day: fatal or life-threatening unexpected SUSARs; 15-day: all other serious unexpected
- Medical review and causality assessment workflow documented
Separate reviewer from intake; documented rationale for causality determination
- Follow-up case process defined
Protocol for obtaining additional information and submitting follow-up ICSRs
- Aggregate reporting obligations assessed
IND Annual Report safety summary; DSUR if applicable for global programs

4 DOCUMENTATION AND TRAINING

- Pharmacovigilance Plan updated to reference E2B(R3) submission path
Must reflect current FDA ESG submission method, not legacy MedWatch PDF process
- SOPs updated for E2B(R3) intake, processing, and submission workflow
Include clock-start criteria, triage, medical review, coding, submission, and follow-up
- Training completed for all staff involved in AE receipt and case processing
Document training completion with date, content covered, and trainer/trainee signature

Safety data exchange agreement (SDEA) reviewed if partnered program

Confirm partner obligations align with E2B(R3) timeline and submission requirements

Audit trail and data integrity controls documented

21 CFR Part 11 compliance: time-stamped, attributable, complete, consistent, enduring records

Need a compliant adverse event intake layer built for your biotech?

AE Connect by QORO Intelligence is purpose-built for small and mid-size IND sponsors. Structured intake, AI-assisted MedDRA coding, case workflow, and E2B(R3) compliant output.

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