FDA – FAERS
(FDA Adverse Event Reporting System)

What is FAERS?

The FDA Adverse Event Reporting System (FAERS) is a database that contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA.

FAERS Electronic Submissions Update

Currently, Premarketing and Postmarketing Safety Reporting can be done through eCTD format or E2B(R2) xml format, respectively.

Effective from April 1st, 2026, all submissions to FAERS must be submitted in **E2B(R3) XML format**.

	CURRENT	FUTURE
Pre-marketing (IND)	eCTD	ICH E2B (R3)
Post-marketing (NDA, BLA, ANDA)	ICH E2B (R2)	ICH E2B (R3)

Companies may choose to submit in ICH E2B (R3) format before the 2026 deadline. However please note that once a company submits in E2B(R3) format, it is not allowed to revert to previous formats or standards.

Submission Portals for FAERS

FAERS with E2B(R3) XML format can be submitted through the **FDA Electronic Submission Gateway (ESG)** or through the **Safety Reporting System (SRP)**.

More information regarding this process can be found at: https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-electronic-submissions

For further information or advice, please contact: info@asphalion.com