FAERS 2026: Adverse Event Report Data, Top Drugs & Outcomes

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Executive Summary

The FDA Adverse Event Reporting System (**FAERS**) has been the primary United States repository of postmarket drug and biologic safety reports since it succeeded the older AERS database. FDA describes FAERS as its primary database for collecting and analyzing adverse event reports, serious medication errors, and product quality complaints for prescription drugs and therapeutic biologics. The single most important fact for anyone searching FAERS data in 2026, however, is that FAERS itself is being absorbed into a larger platform: on March 11, 2026, FDA launched the **FDA Adverse Event Monitoring System (AEMS)**, a unified platform folding FAERS together with the Vaccine Adverse Event Reporting System (VAERS) and the animal drug and food AERS databases, with the Manufacturer and User Facility Device Experience (MAUDE) database following in May 2026 (Source: www.fda.gov). The legacy patchwork of seven adverse event databases processed roughly 6 million reports a year and cost the agency about $37 million annually to run; FDA projects the AEMS consolidation will save approximately $120 million over five years while adding daily public-data publication alongside continuing quarterly raw-data files (Source: www.fda.gov).

Peer reviewed pharmacovigilance studies published in 2024 and 2025 describe FAERS databases containing between 10.1 million and 19.5 million cumulative adverse event reports depending on the study's cutoff quarter (Source: www.nature.com) (Source: bmcpharmacoltoxicol.biomedcentral.com). Drug specific disproportionality analyses continue to identify serious outcome rates that vary sharply by drug class: semaglutide reports showed roughly 18.5 percent serious outcomes with hospitalization the leading category at 14.68 percent (Source: pmc.ncbi.nlm.nih.gov, mepolizumab reports were coded with “other serious outcome” in 56.38 percent of reports (Source: www.frontiersin.org, and combined ipilimumab-nivolumab immunotherapy reports showed 21.8 percent death and 39 percent hospitalization (Source: www.nature.com). Direct oral anticoagulant comparisons found rivaroxaban carried nearly six times the reporting odds of gastrointestinal hemorrhage compared with apixaban (Source: www.ncbi.nlm.nih.gov, while a checkpoint inhibitor study mining 7.9 million FAERS cases found hypophysitis carried a proportional reporting ratio (PRR) of 267.82 in pembrolizumab treated melanoma patients (Source: pmc.ncbi.nlm.nih.gov (Source: pmc.ncbi.nlm.nih.gov).

Signal detection relies chiefly on the Multi-item Gamma Poisson Shrinker (MGPS) algorithm, which produces an Empirical Bayes Geometric Mean (EBGM) score bounded by 90 percent confidence limits designed to suppress false positive signals that a simple Proportional Reporting Ratio would generate from small case counts. This pipeline has driven concrete regulatory action: a 2019 peer reviewed analysis found SGLT2 diabetes drugs carried a PRR of 5 to 10 for Fournier's gangrene after an initial cluster of just 12 reported cases (Source: pmc.ncbi.nlm.nih.gov), and a FAERS-identified signal drove an April 2024 class-wide boxed warning for T-cell malignancies following BCMA- or CD19-directed CAR-T therapies, later followed by a June 2025 easing of the associated Risk Evaluation and Mitigation Strategy (REMS). A parallel signal opened in July 2023 around GLP-1 receptor agonists and suicidal ideation was ultimately reversed after larger studies, including a meta-analysis of 91 trials covering 107,910 patients, failed to confirm it, illustrating that a FAERS signal is a hypothesis rather than a confirmed causal finding (Source: www.fda.gov (Source: pmc.ncbi.nlm.nih.gov).

Behind these regulatory numbers sits a growing commercial pharmacovigilance industry. Market research firms estimate the global PV market at roughly $9.35 billion in 2025, rising to between $10.45 billion and $10.54 billion in 2026 depending on the source, with forecasts diverging sharply thereafter, from $18.26 billion by 2031 to $31.56 billion by 2034 (Source: www.mordorintelligence.com) (Source: www.fortunebusinessinsights.com). Case processing consumes up to two-thirds of internal PV resources according to peer reviewed benchmark data (Source: pmc.ncbi.nlm.nih.gov, and case volumes are growing 10 to 15 percent a year at many manufacturers (Source: www.indegene.com), while a separate industry poll found 84 percent of PV executives reporting a significant five-year increase in their own case volumes (Source: www.arisglobal.com). This is why artificial intelligence adoption for case intake has accelerated. Named deployments at Boehringer Ingelheim, Bristol Myers Squibb, and Bayer report data extraction accuracy up to 90 percent, efficiency gains of 25 percent, and documentation time savings of 23.3 percent respectively (Source: www.arisglobal.com) (Source: www.arisglobal.com). This report walks through FAERS's data architecture, the 2026 transition to AEMS, current report volume and serious outcome statistics, the drugs generating the most reports, the statistical methods used to detect signals, the economics of pharmacovigilance case processing, and five detailed case studies illustrating how this data pipeline has shaped actual regulatory decisions and industry practice.

Introduction and Background

Adverse event reporting is the backbone of postmarket drug safety surveillance in the United States. The **FDA Adverse Event Reporting System (FAERS)** is a database that, in FDA's own description, "contains adverse event reports, medication error reports and product quality complaints resulting in adverse events that were submitted to FDA" for drugs and therapeutic biologic products (Source: www.fda.gov). Reports flow in from health care professionals, patients, and manufacturers, and the database has anchored postmarket signal detection for well over a decade, coded to the international ICH E2B individual case safety report (ICSR) standard.

Anyone searching for "FAERS adverse event report data 2026" in August 2026 needs one fact above all others: FAERS as a standalone system is in the process of being folded into a new, unified platform. On March 11, 2026, FDA officially launched the **FDA Adverse Event Monitoring System (AEMS)**, which its press announcement describes as "a new unified platform for analyzing adverse event reports," folding in FAERS itself, defined in the same announcement as covering "reports for drugs, biologics, cosmetic products, and color additives," alongside VAERS and the animal drug and food AERS databases, with the medical device database MAUDE joining in May 2026 (Source: www.fda.gov).

The transition did not happen overnight. FDA had already begun daily publication of FAERS data on August 22, 2025, as an intermediate step toward the more timely public-data model AEMS now targets; FDA continues to provide quarterly raw-data extracts, with full real time coverage across all FDA-regulated product categories expected by the end of May 2026 (Source: www.fda.gov. None of this diminishes FAERS's data or methodology, both of which persist inside AEMS. The underlying reporting rules, the statistical signal detection machinery described later in this report, and more than fifteen years of historical case data mined in peer reviewed pharmacovigilance research remain the analytical foundation researchers and pharmacovigilance professionals use every day (Source: www.nature.com) (Source: bmcpharmacoltoxicol.biomedcentral.com). This report explains how that foundation works, what the 2026 platform changes mean in practice, which drugs and drug classes are generating the most reports and the most serious outcomes, how signal detection statistics work, what pharmacovigilance case processing costs the industry, and how five real world regulatory and technology cases illustrate the entire pipeline in action.

Inside FAERS: Data Architecture, Reporting Rules, and the 2026 AEMS Transition

FAERS quarterly data extract files, the format most familiar to academic FAERS researchers, were explicitly described by FDA as "raw data extracted from the AERS database for the indicated time ranges" that "are not cumulative," meaning each quarterly file is a standalone snapshot rather than an updated master dataset, distributed in **ASCII** or **SGML** formats that bundle together demographic, drug, reaction, outcome, therapy, indication, and report-source data along with a README file describing the schema (Source: www.fda.gov).

Who reports, and under what obligation. The reporting obligation differs sharply by submitter type. Health care professionals and consumers report voluntarily using **Form 3500** and **Form 3500B** respectively through the MedWatch program; FDA states plainly that "FDA relies on the voluntary reporting of these events" from this group (Source: www.fda.gov). Manufacturers, by contrast, face a **mandatory** obligation using Form 3500A: if a manufacturer receives a report of a suspected adverse event, "it is required to send the report to FDA as specified by regulations" (Source: fis.fda.gov), and expedited (commonly called "15-day") reports apply specifically when the report contains "at least one adverse event that is not currently described in the product labeling" for which "the patient outcome is serious" (Source: www.fda.gov).

What the data cannot do. FDA is unusually explicit about FAERS's analytical limits, and these caveats travel forward into AEMS. The database cannot be used to establish causation, since "there is no certainty that a suspected drug caused the reaction" in any individual report (Source: fis.fda.gov). Because reporting by clinicians and patients is voluntary, FDA states the database "contains only a small fraction of the side effects that occur with a drug" (Source: fis.fda.gov), and consequently the reports "cannot be used to estimate the incidence (occurrence rates)" of any adverse reaction in the treated population (Source: fis.fda.gov. These are not new criticisms invented for this report; they are FDA's own published caveats, and any statistic quoted later in this report should be read through this lens: FAERS counts reports, not confirmed harms.

Historical scope and the AEMS upgrade. The public dashboard has long let users "view a summary of adverse event reports received from 1968 to the present," giving FAERS one of the longest continuous adverse-event time series of any national pharmacovigilance database, a depth of history that underlies the multi-decade drug-specific studies (some spanning 2004 to 2024) discussed throughout this report (Source: fis.fda.gov) (Source: journals.plos.org). This is as much an artificial intelligence and data infrastructure story as a regulatory one, a theme this report returns to in the discussion of AI-driven case processing below.

FAERS Report Volume and Serious Outcomes

FDA's own historical statistics, last published in a static year-by-year format dated November 2015, show total reports entered into FAERS climbing from 335,751 in 2006 to 1,204,685 in 2014 (Source: www.fda.gov). Over the same period, reports coded with a serious outcome, meaning the report documented "death, hospitalization, life-threatening, disability, congenital anomaly and/or other serious outcome," grew from 264,227 to 807,270, and deaths coded within the database rose from 37,309 to 123,927 (Source: www.fda.gov). FDA has not republished an equivalent official year-by-year table covering 2016 through 2026, in part because the platform's attention shifted first to daily publication in August 2025 and then to the AEMS consolidation in March 2026, both of which restructured how aggregate statistics are surfaced.

In the absence of a refreshed official aggregate table, peer reviewed pharmacovigilance studies mining the raw FAERS quarterly files provide the best available picture of recent volume and severity. A 2024 study of avatrombopag drew on a FAERS corpus of 10,118,235 total adverse event reports spanning the second quarter of 2018 through the fourth quarter of 2023 (Source: www.nature.com), while a 2025 empagliflozin study drew on 19,494,698 total FAERS reports from January 2004 through January 2023 (Source: bmcpharmacoltoxicol.biomedcentral.com), and a 2024 Definity ultrasound contrast agent study reported 17,559,535 total FAERS cases from the first quarter of 2004 through the first quarter of 2024 (Source: journals.plos.org). A separate immune checkpoint inhibitor study processed "7.9 million cases (9.5 million reports)" from an earlier full-database extract, and a 2025 combination-therapy study processed 13,038,441 reports from a 2015-to-2024 extract, further confirming this steady multi-year growth trajectory (Source: pmc.ncbi.nlm.nih.gov (Source: www.nature.com). These figures are not directly comparable because each study applies a different cutoff quarter and a different deduplication method, but together they confirm that the cumulative FAERS corpus has grown from roughly 10 million to close to 20 million total reports across the period most relevant to 2026 research.

Serious outcome rates vary enormously by drug and drug class, which is precisely why aggregate, database-wide serious outcome percentages are of limited use to any single manufacturer or regulator. *Table 1* below summarizes selected recent, peer-reviewed serious outcome findings drawn from drug-specific FAERS disproportionality studies.

DRUG OR DRUG CLASS	FAERS REPORTS ANALYZED	REPORTED OUTCOME MEASURE	DEATH OUTCOME (STUDY DENOMINATOR)	HOSPITALIZATION OUTCOME (STUDY DENOMINATOR)	STUDY PERIOD
Avatrombopag (thrombopoietin receptor agonist)	1,217 (Source: www.nature.com	Serious AEs: 404 of 1,217 reports (33.20%)	76 of 404 serious AEs (18.81%)	198 of 404 serious AEs (49.01%)	Q2 2018 to Q4 2023
Mepolizumab (asthma biologic)	18,040 (Source: www.frontiersin.org	Other serious outcome: 10,172 of 18,040 reports (56.38%)	1,362 of 18,040 reports (7.55%)	6,167 of 18,040 reports (34.18%)	Q4 2015 to Q1 2023 (Source: www.frontiersin.org)
Semaglutide (GLP-1 receptor agonist)	14,512 (Source: pmc.ncbi.nlm.nih.gov)	Serious outcomes: 2,687 of 14,512 reports (~18.5%)	not separately reported	14.68% of 14,512 reports (Source: pmc.ncbi.nlm.nih.gov	Q1 2018 to Q2 2023
Ipilimumab plus nivolumab (combined checkpoint inhibitor therapy)	19,462 (Source: www.nature.com)	not separately reported	21.8% of 19,462 reports	39% of 19,462 reports (Source: www.nature.com)	2015 to Q1 2024
Perflutren lipid microsphere (Definity) contrast agent	4,460 (Source: journals.plos.org	Combined serious outcomes: 9.9% of 4,460 reports	Death: 1.7% of 4,460 reports	Hospitalization: 212 of 4,460 reports (4.8%)	Q1 2004 to Q1 2024
Direct oral anticoagulants (bleeding events specifically)	17,236 of 353,188 total hemorrhage reports (Source: pubmed.ncbi.nlm.nih.gov	4.9% of all hemorrhage reports attributed to DOACs	not separately reported	not separately reported	2015 to 2023

The outcome measures in this table use study-specific definitions and denominators; for example, the avatrombopag death and hospitalization percentages are among serious reports, whereas the mepolizumab outcome percentages are among all reports. They therefore should not be compared as like-for-like drug safety rates or treated as representative of the database as a whole (Source: www.nature.com (Source: www.frontiersin.org. Biologics used in severely ill populations, such as mepolizumab in refractory asthma or ipilimumab-nivolumab in advanced cancer, mechanically generate higher serious-outcome shares than a drug used in a broader, healthier population, independent of any question about the drug's actual safety margin (Source: www.nature.com). Report volume for individual drugs also fluctuates with prescribing trends and media attention rather than tracking a constant background rate: the Definity contrast agent study found annual reports rising from 134 in 2004 to a peak of 624 in 2007, collapsing to just 9 in 2011 following a boxed warning label change, and climbing back to 513 and 509 reports in 2022 and 2023 respectively, a pattern consistent with what pharmacovigilance researchers call "notoriety bias" or stimulated reporting (Source: journals.plos.org, a

phenomenon also documented in the same study's discussion of media coverage effects on reporting behavior (Source: journals.plos.org). The mepolizumab study similarly found that reporting climbed steadily from 2015 through 2022 before beginning to plateau, a trajectory the study's authors link to the drug's expanding approved indications over that period (Source: www.frontiersin.org).

Selected Drug Classes in Recent FAERS Research

FDA does not publish a single, current static ranking of drugs by FAERS report volume. The examples below are selected 2024 to 2026 peer-reviewed pharmacovigilance studies; they describe report counts and disproportionality findings for particular products or classes, not a ranking of the drugs with the most FAERS reports.

GLP-1 receptor agonists are the drug class generating the most FAERS-driven research and regulatory attention as of 2026. A study covering the first quarter of 2018 through the second quarter of 2023 identified 14,512 semaglutide-specific reports (Source: pmc.ncbi.nlm.nih.gov) and flagged ten adverse event signals not yet described on the drug's label at the time, including "pancreatic cancer," "intestinal obstruction," "cholecystitis," and "polycystic ovary" (Source: pmc.ncbi.nlm.nih.gov). A separate 2025 disproportionality analysis comparing semaglutide, liraglutide, and tirzepatide found that only semaglutide carried a statistically significant reporting odds ratio (ROR) for depression, at 1.87, and for suicide or self-injury, at 1.73, while the other two GLP-1 drugs in the comparison did not reach significance on the same endpoints (Source: pubmed.ncbi.nlm.nih.gov) (Source: pubmed.ncbi.nlm.nih.gov). A study focused specifically on the oral semaglutide tablet formulation identified 2,398 reports comprising 5,653 distinct adverse event terms across a shorter window from the third quarter of 2019 through the third quarter of 2023 (Source: pubmed.ncbi.nlm.nih.gov) (Source: pubmed.ncbi.nlm.nih.gov).

SGLT2 inhibitors, another major diabetes drug class, generated a comparatively small but highly disproportionate signal for Fournier's gangrene, a rare and severe genital infection: a peer-reviewed analysis of 47 confirmed FAERS cases found a proportional reporting ratio (PRR) of 5 to 10 for the drug class compared with other medications, building on an initial cluster that traced to just 12 reported cases between March 2013 and May 2018 (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov). Separately, an empagliflozin-specific study covering January 2004 through January 2023 identified 20,734 drug-specific reports out of a 19,494,698-report FAERS background (Source: bmcpharmacoltoxicol.biomedcentral.com), and found that 10.19 percent of coded cases (2,112 reports) occurred within the first month of therapy, with a median time to onset of 28 days (Source: bmcpharmacoltoxicol.biomedcentral.com.

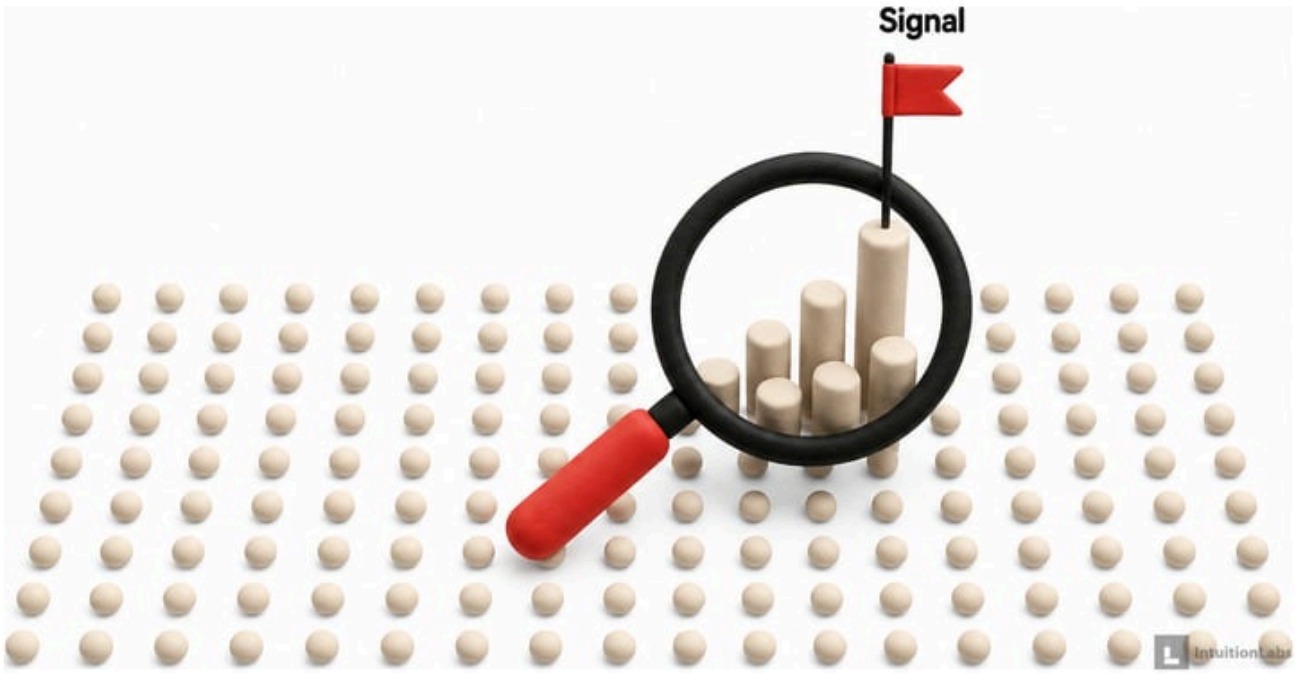
Immune checkpoint inhibitors used in oncology also feature prominently. A foundational study processed "7.9 million cases (9.5 million reports)" from the full public dataset and isolated 2,291 adverse event cases in melanoma patients treated with pembrolizumab (Source: pmc.ncbi.nlm.nih.gov (Source: pmc.ncbi.nlm.nih.gov), finding hypophysitis (pituitary gland inflammation) carried the strongest disproportionality signal of the immune-related adverse events studied, with an FAERS-derived PRR of 267.82 (Source: pmc.ncbi.nlm.nih.gov). Colitis, an adverse event that carries an explicit labeling warning for checkpoint inhibitors, showed a PRR of 35.8 in the same analysis (Source: pmc.ncbi.nlm.nih.gov). A more recent 2025 study of combined ipilimumab-nivolumab therapy, drawing on a 13,038,441-report FAERS background, found reporting volume for the combination peaked in 2023 at 3,419 reports, or 17.6 percent of all combination-therapy reports, with hospitalization noted in 39 percent of reports and death in 21.8 percent (Source: www.nature.com) (Source: www.nature.com.

Anticoagulants round out the drugs most frequently studied through FAERS in recent literature. A disproportionality analysis of direct oral anticoagulants (DOACs) covering 2015 through 2023 found 17,236 of 353,188 total hemorrhagic event reports, or 4.9 percent, attributable to the DOAC class, with edoxaban showing the strongest bleeding signal of the group at a PRR of 14.1 (Source: pubmed.ncbi.nlm.nih.gov (Source: pubmed.ncbi.nlm.nih.gov. A separate 2025 study directly comparing rivaroxaban and apixaban, drawing on 88,026 and 87,490 FAERS reports respectively between January 2012 and March 2024 (Source: www.ncbi.nlm.nih.gov, found gastrointestinal hemorrhage reporting odds nearly six times higher for rivaroxaban, at an ROR of 5.91, and cerebral hemorrhage reporting odds 1.73 times higher, a divergence the study's authors attribute to differing renal clearance profiles between the two anticoagulants (Source: www.ncbi.nlm.nih.gov (Source: www.ncbi.nlm.nih.gov.

Definity's boom-bust reporting pattern documented earlier in this report is itself a peer reviewed illustration of how label changes and media coverage, not just underlying drug safety, shape which drugs dominate FAERS report volume in any given year (Source: journals.plos.org.

Signal Detection and Disproportionality Analysis

FAERS's value is not simply as a repository of individual reports but as a substrate for statistical **signal detection**, the process of identifying drug-event pairs reported more often than would be statistically expected given background reporting rates. FDA is careful to note that "the appearance of drug or biological product on a quarterly report means that FDA has identified a potential safety signal and is evaluating the signal," not that a causal relationship has been confirmed (Source: www.fda.gov). FDA's January to March 2026 quarterly report continued this pattern, listing roughly twenty distinct new potential safety signals across products ranging from Acthar Gel to Rinvoq, most still marked with the standard notation that "FDA is evaluating the need for regulatory action" (Source: www.fda.gov).



The statistical toolkit that supports this decision spans four main disproportionality methods, summarized in *Table 2* below.

METHOD	STATISTICAL BASIS	PRIMARY USER	KEY CHARACTERISTIC
Proportional Reporting Ratio (PRR)	2 by 2 contingency table comparing a drug-event pair against all other drug-event reports, described by FDA as "the foundational concept for many disproportionality methods" (Source: www.fda.gov	Academic FAERS studies, including the SGLT2 and checkpoint inhibitor analyses cited above (Source: pmc.ncbi.nlm.nih.gov)	Simple, transparent, but prone to false positives on small case counts
Reporting Odds Ratio (ROR)	Odds-based variant of the same contingency table logic	Common in recent academic FAERS studies, including the semaglutide, DOAC, and anticoagulant comparisons cited above (Source: pubmed.ncbi.nlm.nih.gov)	Similar interpretation to PRR; frequently reported alongside PRR for cross-validation
Multi-item Gamma Poisson Shrinker (MGPS) / Empirical Bayes Geometric Mean (EBGM)	Bayesian shrinkage applied to reporting ratios, bounded by 90% confidence limits denoted EB05 and EB95, per a peer reviewed FAERS methodology paper describing MGPS as the agency's core routine algorithm (Source: pmc.ncbi.nlm.nih.gov	FDA's primary internal routine data-mining algorithm	Explicitly designed to "diminish the effect of spuriously high PRR values, thus reducing the number of false-positive safety signals" (Source: www.fda.gov)
Bayesian Confidence Propagation Neural Network (BCPNN)	Information Component derived from a Bayesian neural network model	Used in combination with PRR, ROR, and EBGM in multi-method academic validation studies (Source: pubmed.ncbi.nlm.nih.gov)	Typically deployed alongside, not instead of, the other three methods to cross-confirm a signal

Critically, FDA cautions that these methods only generate hypotheses: "the absence of disproportionality does not confirm the absence of a safety signal nor negate a signal detected by other methods," a reminder that clinical trial data, published case reports, and mechanistic plausibility all remain necessary complements to any FAERS-derived statistic (Source: www.fda.gov). In practice, analysts tune their FAERS search strategy along a sensitivity-specificity tradeoff, since "the search strategy may be broad to increase sensitivity or narrow to increase specificity" depending on whether the goal is to catch every possible signal or to minimize false alarms (Source: pmc.ncbi.nlm.nih.gov). A related, independently confirmed pattern illustrating multi-method convergence comes from fluoroquinolone antibiotics and aortic injury: a FAERS data-mining study applying ROR, PRR, BCPNN, and EBGM together analyzed 3,721 adverse event reports from 2004 to 2016 and found that "all three fluoroquinolones are associated with aortic aneurysm, and levofloxacin is associated with aortic dissection" (Source: pubmed.ncbi.nlm.nih.gov).

Data Analysis and Evidence

Behind the regulatory statistics sits a commercial pharmacovigilance industry whose scale has grown in step with FAERS report volume. Market research estimates vary by originator and methodology but broadly agree on the order of magnitude: Mordor Intelligence values the global pharmacovigilance market at $9.35 billion in 2025, rising to $10.45 billion in 2026 and reaching $18.26 billion by 2031, a compound annual growth rate (CAGR) of 11.78 percent (Source: www.mordorintelligence.com). Fortune Business Insights reaches the identical 2025 baseline of $9.35 billion but projects faster growth to $31.56 billion by 2034 at a 14.69 percent CAGR (Source: www.fortunebusinessinsights.com). The divergence between the two firms' 2031 to 2034 endpoints illustrates a broader pattern in PV market sizing: near-term estimates from independent research firms tend to cluster tightly, while long-horizon forecasts diverge sharply based on differing assumptions about biologics pipeline growth and outsourcing penetration (Source: www.mordorintelligence.com) (Source: www.fortunebusinessinsights.com). **Contract outsourcing** already dominates service delivery, holding "54.88% revenue share in 2025" and expanding at a 13.48 percent CAGR of its own, according to Mordor Intelligence (Source: www.mordorintelligence.com). Within the narrower PV outsourcing sub-segment specifically, Precedence Research sizes the 2026 market at $6.24 billion growing to $13.03 billion by 2035 (Source: www.precedenceresearch.com), while Mordor Intelligence's separate outsourcing-specific report sizes the same 2026 market considerably higher at $9.15 billion growing to $18.88 billion by 2031, a discrepancy that underscores how differently research firms scope "outsourcing" within the broader PV category (Source: www.mordorintelligence.com). Fortune Business Insights attributes the wider market's growth specifically to rising regulatory complexity and expanding biologics portfolios across major pharmaceutical markets (Source: www.fortunebusinessinsights.com), while Precedence Research separately frames outsourcing growth as a function of sponsors seeking specialized signal-detection staffing rather than building it in-house (Source: www.precedenceresearch.com).

Case volume growth and case processing cost are the two metrics that matter most to pharmacovigilance operating budgets, and both are trending upward. An industry poll of pharmacovigilance executives found "84% of attendees indicated a significant increase in their case volumes over the last five years" (Source: www.arisglobal.com), and a benchmarking report drawing on Deloitte and ASCPT survey data found case volumes growing "at a rate of 10% to 15% per year" while "40% to 80% of allocated PV budgets" go toward case processing specifically (Source: www.indegene.com). A peer-reviewed study co-authored by Pfizer scientists confirms this from the primary literature, noting that case processing activities "constitute a significant portion of internal pharmacovigilance (PV) resource use, ranging up to two-thirds on the basis of PVNet benchmark data" (Source: pmc.ncbi.nlm.nih.gov. At the individual company level, IQVIA reports that Sanofi's pharmacovigilance operation "manages over 700,000 adverse event reports annually," a figure that gives a sense of scale for what a single large multinational manufacturer's mandatory-reporting obligation looks like in practice and that helps explain the rising demand for outsourced capacity described in the market-sizing figures above (Source: www.iqvia.com) (Source: www.mordorintelligence.com).

Cost per case figures require careful framing, because "cost of an adverse drug reaction" in the clinical literature typically measures the downstream hospitalization or treatment cost of managing the reaction in a patient, not a manufacturer's internal cost of processing the resulting FAERS case report. A systematic review published in the peer-reviewed journal Pharmacoepidemiology found that across studies from 2000 to 2017, "the cost per ADR widely fluctuated from USD 65.00 to USD 12,129.90 based on various factors" (Source: www.mdpi.com), with average costs in high-income countries running roughly ten times higher than in India, specifically "USD 2908.77 to 12,129.90 in high-income countries, and from USD 65.00 to 581.71 in India" (Source: www.mdpi.com). The same systematic review found study heterogeneity itself, differences in what counts as an ADR-attributable cost across health systems, was the largest single driver of the wide range, a methodological caution directly analogous to the cross-study comparability problems this report notes for FAERS report-volume figures (Source: www.mdpi.com). On the manufacturer-side processing cost, industry analysts describe two main levers for cost reduction: automation and geographic arbitrage. Mordor Intelligence reports that "vendors highlight 30% lower cost-per-case when predictive algorithms triage narratives before human medical review" (Source: www.mordorintelligence.com), and separately that "sponsors report 30-40% cost savings from APAC operations, reinforcing the shift of follow-the-sun case-processing models" (Source: www.mordorintelligence.com). The Indegene benchmarking report puts a similar figure on automation specifically, citing an expected "~35% Expected cost reduction due to automation" (Source: www.indegene.com). Structurally, Mordor Intelligence attributes rising demand for outsourced pharmacovigilance capacity to "rising adverse-event volumes linked to complex biologics, oncology therapies, and orphan drugs, creating sustained demand for specialized signal-detection expertise," a trend directly reflected in the biologics-heavy drug list in the previous section (Source:

www.mordorintelligence.com). Indegene's benchmarking work frames this automation-driven cost reduction as most achievable in the case-intake and triage stages specifically, rather than in medical review, which remains labor-intensive regardless of front-end automation (Source: www.indegene.com).

AI-driven case processing is the industry's primary response to rising volume and cost pressure, and both regulators and industry are moving in parallel. FDA's own 2023 discussion paper, revised in February 2025, states that "there are potential opportunities to use AI/ML for automation during ISCR processing," breaking the opportunity down into "case validity, case prioritization, duplicate check, coding, and quality control" (Source: www.fda.gov). CDER's Emerging Drug Safety Technology Program (EDSTP) confirms industry is already moving in this direction, noting that "early adopters of AI are leveraging these emerging technologies to automate fundamental tasks" in postmarket safety surveillance (Source: www.fda.gov). In Europe, the EMA's July 2023 reflection paper on artificial intelligence across the medicinal product lifecycle explicitly names "pharmacovigilance activities including adverse event report management and signal detection" as a post-authorization AI use case (Source: www.ema.europa.eu), while insisting that "a human-centric approach should guide all development and deployment of AI and ML" in this space (Source: www.ema.europa.eu). Industry governance frameworks are catching up in parallel: a 2025 CIOMS Working Group XIV draft report, summarized by law firm Sidley Austin, frames the core compliance question for any PV automation deployment as whether "an AI system in PV is 'high-risk'," which "depends on its specific use" rather than on the underlying technology alone (Source: datamatters.sidley.com). Consistent with this pattern, the JMIR-published Bayer MyGenAssist study evaluates its own internal AI tool within Bayer's existing pharmacovigilance quality system rather than as a freestanding technology (Source: pmc.ncbi.nlm.nih.gov, and the earlier Genpact-Bayer PVAI deployment was likewise framed by Bayer's own pharmacovigilance leadership as augmenting, not replacing, the existing case-processing operating model (Source: media.genpact.com).

Case Studies and Real-World Examples

GLP-1 Receptor Agonists: A Signal Opened, Investigated, and Partly Reversed

In July 2023, "after receiving postmarketing reports of SI/B in patients taking GLP-1 RA medications, FDA initiated further investigation" into suicidal ideation and behavior (SI/B) across the entire GLP-1 receptor agonist class, including semaglutide (Ozempic, Wegovy), liraglutide (Saxenda), and tirzepatide (Zepbound) (Source: www.fda.gov). The eventual outcome illustrates why FDA repeatedly cautions that a FAERS signal is a hypothesis, not a conclusion: after a comprehensive meta-analysis of 91 clinical trials covering 107,910 patients and a separate Sentinel System cohort study of over 2.2 million users, FDA reversed course and formally requested "that drug application holders remove information regarding the risk of suicidal ideation and behavior (SI/B) from the labeling" for Saxenda, Wegovy, and Zepbound (Source: www.fda.gov. Not every signal in this drug class was reversed: FDA's own quarterly signal tracker shows that alopecia was added to the labeling of nine GLP-1 products between December 2024 and May 2025, and FDA separately required a postmarketing trial to "measure the effects of temporary withholding of GLP-1 receptor agonists and fasting duration on retained gastric contents" after an aspiration-risk signal (Source: www.fda.gov). Trade press separately documented an ileus (intestinal blockage) warning added to Ozempic's label in September 2023 following review of postmarketing reports (Source: www.hcplive.com, a pattern of newly emerging gastrointestinal signals also flagged in the independent academic disproportionality literature discussed earlier in this report (Source: pmc.ncbi.nlm.nih.gov). Taken together, the GLP-1 case demonstrates both the strength and the limits of FAERS driven signal detection within a single drug class over roughly three years.

CAR-T Cell Therapies: Boxed Warning Followed by REMS Rollback

Chimeric antigen receptor (CAR-T) cell therapies targeting BCMA or CD19, including Abecma, Breyanzi, Carvykti, Kymriah, Tecartus, and Yescarta, illustrate how a FAERS signal can move from initial alert to formal labeling change to a later easing of risk mitigation as more real-world experience accumulates. FDA's own T-cell malignancy safety review states plainly that the agency "also listed post-treatment T cell malignancy as a potential signal of serious risk/new safety information for this product class, identified by FDA Adverse Event Reporting System (FAERS) in the July - September 2023" reporting quarter, and that by April 2024 the agency required a class-wide boxed warning after concluding that "mature T cell malignancies, including CAR-positive tumors, may present as soon as weeks following infusion, and may include fatal outcomes" (Source: www.fda.gov (Source: www.fda.gov). By June 2025, FDA reversed a separate risk mitigation requirement for the same six products, eliminating the Risk Evaluation and Mitigation Strategy (REMS) that had required certified treatment centers to keep the interleukin-6 blocker tocilizumab on site, on the grounds that "physicians and institutions now have greater experience identifying and managing toxicities with the currently approved CAR T products" (Source: www.fda.gov).

Ranitidine (Zantac): A Withdrawal Driven by Chemistry, Not Disproportionality

Ranitidine's 2020 market withdrawal is one of the most consequential postmarket safety actions of the past decade, and it is instructive precisely because it did **not** originate from FAERS disproportionality analysis. On April 1, 2020, FDA requested that "manufacturers withdraw all prescription and over-the-counter (OTC) ranitidine drugs from the market immediately" (Source: www.fda.gov. The scientific trigger was laboratory testing showing that "the impurity in some ranitidine products increases over time and when stored at higher than room temperatures and may result in consumer exposure to unacceptable levels" of the probable carcinogen N-nitrosodimethylamine (NDMA), a product-quality and chemical-stability finding rather than a spontaneous adverse-event reporting signal (Source: www.fda.gov). The case is a useful counterpoint to the other examples in this section: not every major postmarket drug safety action traces back to a FAERS statistical signal, and treating FAERS disproportionality as the only pathway to regulatory action would understate how much of postmarket surveillance still depends on manufacturing quality testing, inspections, and other non-spontaneous-report data sources.

SGLT2 Inhibitors and Fournier's Gangrene: A Compact Signal-to-Label Pipeline

Where the GLP-1 and CAR-T cases show extended, multi-year signal evaluation, the SGLT2 inhibitor and Fournier's gangrene case is a comparatively fast and textbook example of the FAERS signal detection pipeline in miniature. The FAERS-derived evidence traced to just twelve initial cases reported between March 2013 and May 2018, and a subsequent peer-reviewed disproportionality analysis of the wider case series, 47 confirmed cases in total, confirmed the strength of the signal, finding "increased reporting frequency emerged for SGLT2i compared with other drugs, with a PRR ranging from 5 to 10" (Source: pmc.ncbi.nlm.nih.gov). A related, independently confirmed pattern comes from fluoroquinolone antibiotics and aortic injury: a multi-method FAERS analysis of 3,721 adverse event reports from 2004 to 2016 found that "all three fluoroquinolones are associated with aortic aneurysm, and levofloxacin is associated with aortic dissection" (Source: pubmed.ncbi.nlm.nih.gov). Both cases involved comparatively small absolute case counts, a few dozen to a few thousand reports, that nonetheless produced statistically robust disproportionality scores once compared against appropriate background reporting rates, illustrating that FAERS signal strength depends on relative reporting frequency, not on raw report volume alone.

AI-Driven Case Processing in Practice: Boehringer Ingelheim, Bristol Myers Squibb, and Bayer

Rising case volume and the high share of PV budgets consumed by case processing, up to two thirds per the PVNet benchmark cited earlier, have pushed several large manufacturers to deploy artificial intelligence directly inside their case intake workflows (Source: pmc.ncbi.nlm.nih.gov. In July 2025, Boehringer Ingelheim implemented ArisGlobal's LifeSphere NavaX generative-AI powered "Advanced Intake" tool for individual case safety report processing; within weeks of go-live, the deployment reportedly reached "up to 90% average data extraction accuracy," according to the vendor's press release quoting Boehringer Ingelheim's Head of Patient Safety and Pharmacovigilance (Source: www.arisglobal.com), who said "we are unlocking the potential of AI and automation to transform how our teams process cases" (Source: www.arisglobal.com). Bristol Myers Squibb's Patient Safety team pursued a similar path with a different vendor structure, partnering "with ArisGlobal as their technology provider and Accenture as their business process outsourcing partner" to re-engineer case intake and processing (Source: www.arisglobal.com), a deployment the companies describe as having "Achieved 25% Efficiency Gains in PV Case Intake and Processing" (Source: www.arisglobal.com).

Bayer offers the earliest and the most rigorously studied example in this space. In 2018, Bayer signed a multi-year agreement with Genpact to apply its Pharmacovigilance Artificial Intelligence (PVAI) suite to Bayer's case database, becoming one of the first companies "going live with Genpact's AI-based Case Management module" (Source: media.genpact.com), with Bayer's global head of pharmacovigilance framing the goal as an "opportunity to further increase the efficiency of our pharmacovigilance operating model and case processing" (Source: media.genpact.com). More recently, Bayer built its own internal generative AI tool, MyGenAssist, based on ChatGPT-4 Turbo and integrated with the Oracle Argus safety database. A peer-reviewed 2025 crossover study published via JMIR and mirrored on PubMed Central measured its effect on PV documentation directly, finding "23.3% (95% CI 13.8%-32.8%) of time saving was made thanks to MyGenAssist" on case-related letter drafting, with no significant drop in reporter response rates (Source: pmc.ncbi.nlm.nih.gov, and noting the tool "only required a 2-hour training session for the pharmacovigilance team" to adopt (Source: pmc.ncbi.nlm.nih.gov). Because this is one of the few AI-in-pharmacovigilance results published in the peer-reviewed literature rather than as a vendor case study, it carries more independent evidentiary weight than the Boehringer Ingelheim and Bristol Myers Squibb figures, which originate from vendor press materials and should be read as such (Source: www.arisglobal.com). Across all three deployments, the technology vendor of record for the case-management software itself, whether ArisGlobal or Genpact, describes its role as a platform and services partner rather than a co-developer of the underlying pharmacovigilance decision-making, a distinction Bristol Myers Squibb's joint filing with ArisGlobal and Accenture makes explicit by naming separate technology and business-process-outsourcing partners for the same deployment (Source: www.arisglobal.com).

Implications and Future Directions

The convergence of two trends, rising FAERS case volume on one side (Source: www.arisglobal.com) and maturing AI-based case processing tools on the other (Source: pmc.ncbi.nlm.nih.gov, points toward a pharmacovigilance function that looks structurally different by the end of the decade than it did even three years ago. FDA's daily public-data publication, which began in August 2025, can change how signal detection is practiced: analysts and automated systems may work against a moving dashboard dataset, while quarterly raw-data extracts remain available for reproducible file-based analyses.

For pharmaceutical and life sciences organizations, this shift creates two distinct but related operational challenges. The first is data infrastructure: teams that built reporting and signal-monitoring workflows around static quarterly ASCII or SGML files should account for the continuously updated public dashboard and real-time publication model. FDA said enhanced APIs and data-analytics tools would be rolled out in the months following the AEMS launch; it did not establish a public production API as an immediate operational requirement. Genpact's own framing of its earliest FAERS-adjacent AI work with Bayer, as a co-innovation partnership rather than an off-the-shelf tool purchase, suggests that successful integrations in this space have historically required sustained joint engineering rather than a single software procurement decision (Source: media.genpact.com). The second is governance: as the EMA's reflection paper makes clear, deploying AI within a regulated pharmacovigilance workflow, whether for case intake triage, duplicate detection, or coding, requires a risk-based credibility framework matched to the specific context of use, not a one-size-fits-all validation approach (Source: www.ema.europa.eu). Organizations considering data integrations should evaluate their existing safety systems, data models, validation requirements, and the availability of FDA interfaces as they are released. FDA's March 2026 announcement said enhanced APIs would be rolled out in the months ahead, so organizations should not assume a public production API is already available.

Consultancies that specialize in life sciences technology integration, rather than in selling pharmacovigilance case-management software directly, occupy a useful advisory position in this transition: helping organizations map existing Veeva, data engineering, and AI investments against the specific compliance requirements a regulated pharmacovigilance workflow demands. IntuitionLabs, for example, describes its work as helping pharmaceutical and life science clients "leverage AI, GenAI, and advanced analytics for KOL segmentation, chatbots, sales operations, and more," built around solutions with "built-in compliance with FDA, EMA, and global regulations" as a starting design constraint rather than an afterthought (Source: intuitionlabs.ai) (Source: intuitionlabs.ai). This kind of adjacent advisory role, rather than direct sale of a pharmacovigilance case-management platform, is representative of how life sciences consultancies are positioning themselves around the AEMS transition: as integrators and compliance advisors working alongside the case-management vendors named throughout this report, rather than as competitors to them.

Looking ahead, three developments merit close monitoring through the remainder of 2026. First, whether FDA publishes an updated, official aggregate statistics table for AEMS-era report volume and serious outcomes, replacing the stale November 2015 static tables that researchers have relied on for over a decade. Second, whether the October 1, 2026 ICH E2B(R3) electronic submission compliance deadline proceeds on schedule or slips, given the scale of the concurrent AEMS platform migration (Source: www.fda.gov. Third, whether the efficiency gains reported in early AI case-processing deployments, 23.3 percent documentation time savings at Bayer, 25 percent efficiency gains at Bristol Myers Squibb, and up to 90 percent extraction accuracy at Boehringer Ingelheim, persist and generalize once these tools operate at full production scale across a wider range of manufacturers, rather than in the pilot and early-adopter deployments documented so far (Source: www.arisglobal.com) (Source: pmc.ncbi.nlm.nih.gov.

Frequently Asked Questions (FAQs)

What is FAERS and is it still active in 2026? FAERS is FDA's postmarket database of adverse event, medication error, and product quality reports for drugs and therapeutic biologics. As of March 11, 2026, FAERS is being absorbed into the unified FDA Adverse Event Monitoring System (AEMS), but the underlying FAERS data, reporting rules, and signal detection methodology continue to operate within the new platform.

What are the current FDA adverse event reporting system statistics? FDA's most recent official year-by-year aggregate table, dated November 2015, showed reports entered growing from 335,751 in 2006 to 1,204,685 in 2014 (Source: www.fda.gov). More recent peer-reviewed studies mining the raw quarterly files report cumulative FAERS totals ranging from roughly 10.1 million reports (through Q4 2023) to 19.5 million reports (through early 2023 to 2024), depending on the study's cutoff quarter (Source: www.nature.com) (Source: journals.plos.org).

Which drug classes are represented in recent FAERS research? FDA does not publish a single, current ranking of drugs by FAERS report volume. Recent peer-reviewed studies discussed here examine GLP-1 receptor agonists, SGLT2 inhibitors, immune checkpoint inhibitors, and direct oral anticoagulants, but research attention is not evidence that these classes receive the most reports (Source: pmc.ncbi.nlm.nih.gov) (Source: pmc.ncbi.nlm.nih.gov.

What percentage of FAERS reports involve death or hospitalization? These percentages vary by drug, study period, outcome definition, and denominator. Table 1 identifies each study's denominator; its percentages are not directly comparable across rows and cannot estimate incidence or establish a drug caused an event (Source: journals.plos.org (Source: www.frontiersin.org.

How do FAERS quarterly data files work, and are they still published? FAERS quarterly extract files are raw, non-cumulative ASCII or SGML snapshots covering demographic, drug, reaction, outcome, therapy, indication, and report-source data. FDA began daily publication of FAERS adverse-event data in August 2025, while its AEMS site continues to provide the quarterly raw-data files; daily dashboard publication and quarterly extracts serve different access needs.

What is pharmacovigilance case volume growth trending like, and how much does case processing cost? Case volumes are reported growing 10 to 15 percent per year at many organizations (Source: www.indegene.com), with 84 percent of surveyed PV executives reporting a significant five-year increase in their own case volumes (Source: www.arisglobal.com). Manufacturer-facing case-processing cost figures are not consistently published, but industry estimates suggest AI-based triage can lower cost per case by roughly 30 percent and that offshoring case processing to Asia-Pacific hubs can save 30 to 40 percent versus onshore operations (Source: www.mordorintelligence.com) (Source: www.mordorintelligence.com). Related clinical-cost literature on managing an adverse drug reaction once it occurs shows costs ranging from $65 to over $12,000 per case, depending heavily on country income level and clinical setting (Source: www.mdpi.com).

What is FAERS signal detection and disproportionality analysis? Signal detection is the process of identifying drug-event pairs reported more often than statistically expected, using methods including PRR, ROR, MGPS/EBGM, and BCPNN. FDA publishes a quarterly potential-signals report summarizing the results, most recently covering January to March 2026 (Source: www.fda.gov).

Can AI replace human review in FAERS-related pharmacovigilance case processing? Not under current regulatory frameworks. Both FDA's discussion paper and the EMA's reflection paper describe AI as a tool to automate specific sub-tasks such as case validity checks, duplicate detection, and coding, while explicitly requiring "a human-centric approach" to development and deployment (Source: www.ema.europa.eu). Documented deployments at Boehringer Ingelheim, Bristol Myers Squibb, and Bayer all describe AI as accelerating or supporting human case processors, not replacing the medical review step (Source: pmc.ncbi.nlm.nih.gov.

How reliable are FAERS-based statistics compared with clinical trial data? Less reliable for estimating true incidence, but valuable for hypothesis generation. Peer reviewed FAERS methodology work stresses that search strategy choices trade off sensitivity against specificity (Source: pmc.ncbi.nlm.nih.gov), and disproportionality studies across drug classes as different as SGLT2 inhibitors and checkpoint inhibitors converge on the same caveat: a strong statistical signal identifies where to look, not proof of what caused the reaction.

What was Sanofi's reported FAERS-related report volume, and how does it compare to industry benchmarks? IQVIA reports Sanofi alone manages over 700,000 adverse event reports annually (Source: www.iqvia.com), a volume consistent with industry-wide case growth estimated at 10 to 15 percent per year (Source: www.indegene.com) and with the Pfizer-authored finding that case processing consumes up to two-thirds of internal PV resources at large manufacturers (Source: pmc.ncbi.nlm.nih.gov.

How big is the pharmacovigilance outsourcing market, and which firms cover it? Estimates diverge by originator: Precedence Research sizes the 2026 PV outsourcing market at $6.24 billion (Source: www.precedenceresearch.com), Mordor Intelligence sizes the same segment at $9.15 billion (Source: www.mordorintelligence.com), and Fortune Business Insights, which scopes the broader PV market rather than outsourcing alone, projects $31.56 billion by 2034 (Source: www.fortunebusinessinsights.com).

Which companies have publicly documented AI deployments for FAERS-related case processing? Documented, named deployments include Bayer's 2018 Genpact PVAI partnership (Source: media.genpact.com) and its own MyGenAssist generative AI tool (Source: pmc.ncbi.nlm.nih.gov, Boehringer Ingelheim's 2025 ArisGlobal LifeSphere NavaX rollout (Source: www.arisglobal.com), and Bristol Myers Squibb's joint ArisGlobal and Accenture deployment (Source: www.arisglobal.com).

Conclusion

FAERS remains, in substance if not in standalone name, the analytical foundation of United States postmarket drug safety surveillance heading into the second half of 2026. Its historical data, reporting rules, and statistical signal detection machinery, including the MGPS/EBGM algorithm at the center of routine screening, persist as AEMS adds daily public-data publication while FDA continues to provide quarterly raw-data files. FDA also announced plans to roll out enhanced APIs and data-analytics tools in the months following launch. The practical stakes of this transition are considerable: a legacy infrastructure that cost roughly $37 million a year to operate across seven fragmented databases is being consolidated into a

single platform FDA projects will save approximately $120 million over five years (Source: www.fda.gov), while simultaneously closing the gap between when an adverse event is reported and when it becomes visible to regulators, researchers, and the public, a shift that the growing outsourced pharmacovigilance market is itself organizing around (Source: www.mordorintelligence.com).

The drug-specific evidence surveyed in this report, spanning GLP-1 receptor agonists, SGLT2 inhibitors (Source: pmc.ncbi.nlm.nih.gov), immune checkpoint inhibitors, CAR-T cell therapies, and anticoagulants (Source: www.ncbi.nlm.nih.gov, demonstrates that FAERS-derived disproportionality analysis continues to generate real regulatory consequences: boxed warnings, REMS modifications, and in some cases the removal of previously added warnings once larger, more rigorous studies fail to confirm an initial signal. At the same time, the ranitidine case is a necessary caution against overreading FAERS as the sole engine of postmarket drug safety action; product-quality testing, inspections, and clinical trial data remain equally important levers.

For pharmaceutical and life sciences organizations, the more immediate operational question is less about the statistics and more about readiness: whether existing case intake, coding, and signal-monitoring infrastructure can adapt to a real time data environment, and whether AI-assisted case processing, already showing double-digit efficiency gains at early-adopter organizations like Bayer, Boehringer Ingelheim, and Bristol Myers Squibb, can be deployed within the risk-based governance frameworks both FDA and EMA are actively developing (Source: www.ema.europa.eu). Organizations that treat the 2026 AEMS transition purely as a data-format change are likely to underestimate its scope; those that treat it as an occasion to modernize case processing, signal detection, and compliance workflows together stand to capture the larger efficiency and safety-surveillance gains the platform is designed to enable.

Tags: faers, fda adverse event reporting system, pharmacovigilance, adverse event reporting, aems, drug safety signals, disproportionality analysis, pharmacovigilance automation, fda faers data 2026, signal detection

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