



EvaluatePharma®

# Adverse Events

A collaboration with  
AdverseEvents, Inc.



# Adverse Events

Adverse events submitted to FDA through the FDA Adverse Event Reporting System (FAERS) can provide critical insight into the emerging adverse event profile of marketed drugs.

Evaluate have collaborated with AdverseEvents, Inc. (AEI) to provide a truly unique service that combines AEI's high quality FAERS post-approval safety data and proprietary analyses with the power of EvaluatePharma® commercial intelligence and evaluation tools. This resource can be used to understand emerging adverse event trends, conduct comparative safety assessments of drugs through access to statistical severity rankings and the ability to predict future regulatory action. This insight can finally be leveraged in commercial assessments, licensing/M&A, competitive positioning, clinical trial designs and safety monitoring.

Gain **competitive advantage** with fast and easy access to FAERS post-approval safety data, all integrated within EvaluatePharma® to help you manage risk and optimise R&D and commercial performance.

## Key Features:

- Standardized, high quality FAERS data with up-to-date FOIA (Freedom of Information Act) requests
- Proprietary scores of relative safety and signals of potential future drug label risks
- Inclusion of adverse event incidence rates per 100,000 patients treated
- Classification of adverse events as 'on-label' or 'non-label' depending on whether they appear on the current drug label
- Adverse events defined as serious or non-serious and exclusion of disease-related adverse events
- Screen for class effects across multiple drugs from similar groups
- Screen for patient demographics susceptibility to adverse event
- Comparisons by Indication, Pharmacological Class and EphMRA codes
- Company portfolio and product safety profiles for comparative benchmarking
- Custom analytical services performed by credentialed experts





### Key Benefits:

- Accessible, Actionable FAERS
- Optimised Positioning & Labeling
- Risk Assessment in Investment Decisions
- Essential Competitive Intelligence
- Insights for Clinical Trial Planning
- Proactive Product Warning Signals



#### Commercial Insights Teams

Provide your internal customers with product safety insights that are easy to interpret and incorporate into internal models.



#### Business Development Teams

Optimise in-licensing and acquisitions by assessing risk through comparative benchmarking using the same FDA adverse events reports regulators see.



#### Clinical Trial Project Teams

Design clinical trials with safety in mind incorporating enhanced safety monitoring plans and risk mitigation strategies that save R&D costs.



#### Launch, Brand and Marketing Teams

Assess your product's safety profile and label against peers to optimise product positioning and manage product risk.



#### Pharmacovigilance Teams

Integrate easy-to-access FAERS data into your existing Pharmacovigilance programme to identify safety problems and manage risk across product lifecycle.



Evaluate is the trusted provider of commercial intelligence including product sales and consensus forecasts to 2024 for commercial teams and their advisors within the global life science industry. We help our clients make high value decisions through superior quality, timely, must-have data and insights, combined with personalised, expert client support.

**EvaluatePharma**<sup>®</sup> delivers exclusive consensus sales forecasts and trusted commercial insight into biotech and pharmaceutical performance.

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**EP Vantage** an award winning editorial team, provides daily commentary and analysis with fresh perspectives and insight into current and future industry trends.

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**Evaluate Custom Services** provides customised solutions to help you access, analyse and manage the information you need to support effective decision-making.

The Evaluate services enable the life science community to make sound business decisions about value and opportunity.

**AdverseEvents, Inc.** is a California-based healthcare informatics company that improves patient safety and reduces systemic healthcare costs through the comprehensive analysis of post-marketing drug side effect data. Utilizing data-mining and analysis technology, through its proprietary RxSuite™ of analytics, AEI makes post-marketing drug safety data accessible, actionable, and predictable. For more information please visit:

[www.adverseevents.com](http://www.adverseevents.com)

 [@adverseevent](https://twitter.com/adverseevent)



[www.evaluate.com](http://www.evaluate.com)

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