

ORACLE HEALTH SCIENCES EMPIRICA SIGNAL

KEY FEATURES

- Customizable, easy-to-use drug profile portal
- Enhanced, configurable workflow
- Support for a full range of statistical techniques
- Enhanced, higher-performance logistic regression
- Bayesian Multi-Item Gamma Poisson Shrinker interaction calculations for runs with three or more dimensions
- Direct access to safety data through drill-down and case series features
- Streamlined interface
- Interactive reporting with parameter-driven case selection
- Options to download data and case details in native Microsoft Excel (.xls), .pdf, or rich text (.rtf) format
- Robust, comprehensive online help

KEY BENEFITS

- Identify and monitor safety trends using the same tools used by regulators
- Prioritize and execute critical pharmacovigilance activities
- Employ a variety of classical and Bayesian data mining techniques
- Analyze both drug/event combinations and drug/drug interactions
- Filter out false positives to focus on the most important risks
- Detect problems that may have been overlooked during clinical development
- Gather intelligence on competing drugs' safety profiles
- Maintain a comprehensive history of safety-related topics
- Track signals and manage actions in a regulatory-complaint environment

Oracle Health Sciences safety solutions are designed to help companies manage their pharmacovigilance activities proactively and strategically. Oracle Health Sciences Empirica Signal provides a dynamic, visual data mining environment for detecting signals, uncovering patterns, and recognizing emerging trends in spontaneous adverse event report data. Providing pharmacovigilance professionals with the tools they need to effectively, efficiently, and expeditiously manage the review, processing, and response to safety signals, Oracle Health Sciences Empirica Signal eases the process of postmarketing surveillance for pharmaceutical companies.

Increasing Focus on Product Safety

Ongoing and increasing government and public concern about product safety has heightened the importance of pharmacovigilance activities and highlighted the limitations of traditional methods such as individual case review. Today's zero-tolerance drug safety environment calls for new strategies to proactively identify and expeditiously manage safety risks.

In this highly competitive and risk-averse environment, it's essential for pharmaceutical companies to establish pharmacovigilance programs that capitalize on the best available information from multiple data sources. They must also use the most advanced set of tools available for developing a thorough and well-understood safety profile.

Oracle provides pharmacovigilance and risk management solutions that deliver adverse event management, risk management, data mining, signal detection, and signal management capabilities that help companies identify potential safety problems and manage risk effectively across the full product lifecycle.

With its ability to access both external public and internal proprietary databases, Oracle Health Sciences Empirica Signal

- Includes configurations and time-stamping capabilities to support analyses in different databases and between different points in time
- Takes advantage of public data sources including FDA data from the Adverse Event Reporting System (AERS) and Vaccine Adverse Event Reporting System (VAERS) databases, the Vigibase ADR (adverse drug reaction) database from the WHO Collaborating Center for International Drug Monitoring, as well as proprietary internal databases
- Provides drill-down capabilities to display case details collected in case reporting systems

Signal Management

The Oracle Health Sciences Empirica Signal Management module lets users integrate quantitative signal detection techniques into their organizations' routine safety reviews. This enables safety reviewers to assess the latest safety information available for all marketed products and understand how signals evolve as data accumulates.

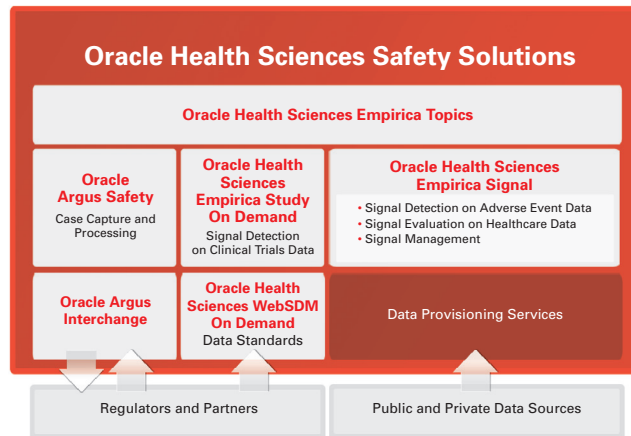


Figure 1. Oracle Health Sciences Empirica Signal is just one of the Oracle Health Sciences safety solutions designed to help pharmaceutical companies identify potential safety problems and manage risk effectively across the full product lifecycle.

Melding Oracle Health Sciences Empirica Signal with a workflow-enabled framework for classifying and documenting the output and conclusions of earlier reviews, Oracle Health Sciences Empirica Signal Management integrates quantitative signal scores with other relevant drug information such as assessments of listedness, seriousness, and public health impact.

Providing a powerful toolbox that scales to support the largest safety departments, a hosted application that allows for flexibility in smaller organizations, and user-customizable data views, Oracle Health Sciences Empirica Signal Management delivers

- Timely detection of new signals and identification of significant changes in signal profiles
- One-click access to a graphical overview of product profiles in Oracle Health Sciences Empirica Signal
- Full access to data mining and signal detection results for drugs of interest on the Drug Overview page
- A filter-by-comments feature for categorizing and selecting relevant signals
- Enhanced commenting abilities that allow blanket comments for multiple drug-event combinations, private comments, and listings of comments
- Structured online assessment, tracking, and prioritization tools
- Workflow and collaboration features for coordinating quantitative signal detection with other pharmacovigilance activities
- Support for multiple publishable Oracle Health Sciences Empirica Signal Management configurations (system or group level)

COMPREHENSIVE SERVICES AND SUPPORT

To maximize your investment in Oracle Health Sciences Empirica Signal, you can draw on a range of Oracle services and support. Expert consulting: Oracle professionals can help you get the most out of Oracle Health Sciences Empirica Signal by

- Data subscription services: Oracle Health Sciences offers subscriptions to FOI AERS data which has been cleaned and optimized for data mining, including drugs coded with generic and trade names, with latest follow-up reports identified and flags of likely duplicates

Maximizing Resources

Oracle Health Sciences Empirica Signal provides users with trusted, cutting-edge technology for signal detection and management. The system mines drug safety data for signals of adverse events that may be occurring more often than expected in corporate and public databases like the FDA AERS or WHO Vigibase. Once identified, signal strength is quantified in a numerical scale and depicted graphically for ease of use and rapid assessment. Changes in signals can be monitored as they develop over time. With Oracle Health Sciences Empirica Signal, drug developers can adopt a more comprehensive approach to proactively manage risk through strategic pharmacovigilance. As a result, safety professionals can work smarter, not harder.



Figure 2. The Drug Profile display provides a user-configurable view of several key visualizations using current data for products of interest to a safety reviewer.

Uncovering Patterns and Trends

Oracle Health Sciences Empirica Signal detects and quantifies safety signals by using advanced data mining techniques that can be applied to any spontaneous reporting database. Signal strength is derived by looking systematically at all the possible drug-event combinations occurring in adverse event reports. Disproportionality analysis identifies suspect drug-event pairs. Leading pharmaceutical safety groups and regulators (including the FDA and the Medicines and Healthcare products Regulatory Agency (MHRA) use data mining technology from Oracle Health Sciences Empirica Signal to identify unexpectedly frequent combinations of drugs and events, and to organize, identify, and analyze patterns in safety data.

Viewing Data Mining Results

Oracle Health Sciences Empirica Signal provides a drug portal interface that avoids the complexities of mining while clarifying key safety indicators at a glance, offering a quick and consistent view across users and drugs. Users can review scores in a tabular or graphical format and drill down to underlying case details.

Oracle Health Sciences Empirica Signal's graphical tools include a robust set of graphs for viewing data mining results (including nested confidence interval graphs for 3-D and 4-D runs), and bar graphs for logistic regression (LROR), proportional report ratio (PRR), and reporting odds ratio (ROR) scores. Users can also organize runs, case series, reports, and saved lists into groups.

Oracle Health Sciences Empirica Signal supports a variety of statistical algorithms—including the acclaimed Bayesian Multi-Item Gamma Poisson Shrinker (MGPS) algorithm created by Dr. William DuMouchel—on postmarketing adverse event report data to produce statistical scores. Detection thresholds are user-defined, allowing a customized balance between scores. Detection thresholds are user-defined, allowing a customized balance between sensitivity and specificity. Whenever these thresholds are exceeded, reviewers are alerted, helping them prioritize or accelerate further analysis. Users can also access logistic regression analysis to isolate the effects of individual drugs in polytherapy situations. Oracle Health Sciences

RELATED PRODUCTS

Oracle Health Sciences safety solutions for pharmacovigilance and risk management include

- **Oracle Health Sciences Empirica Study On Demand.** Signal detection from clinical trials data.
- **Oracle Health Sciences Empirica Topics.** Lifecycle signal tracking and resolution.
- **Oracle Argus Safety.** Case capture and processing.
- **Oracle Argus Safety Japan.** Case capture and processing specific to Japan's PMDA requirements
- **Oracle Argus Interchange**
- **Oracle Health Sciences WebSDM On Demand.** Data standards.

THE OWNERSHIP EXPERIENCE

Staffed by professionals with extensive pharmaceutical, biotechnology, development, and IT experience, Oracle Health Sciences provides one of the most robust cloud applications service offerings in the industry that can scale to the demands of the most complex studies. With Oracle Health Sciences, clients enjoy lifecycle project management, study design and implementation, site and user provisioning, out-of-the-box integrations, hosting and application management, user training, and 24x7 global support.

Empirica Signal has been designed for use in a 21 CFR 11–compliant environment. Oracle Health Sciences’ expert research and development program actively provides continuous enhancement to its cutting-edge signal detection tools.

Using Topic Tracker to Document Investigations and Actions

Oracle Health Sciences Empirica Signal’s enhanced Topic Tracker feature allows safety experts to create records of signals and other safety-related topics of interest—including those identified outside the Oracle Health Sciences Empirica Signal environment. This feature enables users to collect supporting analyses and documentation using configurable signal management workflow capabilities to direct responses.

Driving Pharmacovigilance Productivity

Oracle Health Sciences Empirica Signal Management provides a structured workbench environment where users can assess potential signals—monitoring signals over time, prioritizing work, and routing, tracking, and documenting actions and responses. Safety reviewers can configure the system so they have direct access to the most current and relevant information about the drugs they are monitoring.

For end users, the central component of the system is the Drug Overview page, where they can review results, sector maps, notes and comments, age group breakdowns, interactions, and drug event combinations. A key feature of this page is the Signal Status Table (Figure 3), which presents an integrated view of current safety signals with their history and trends, as well as important contextual information such as seriousness and expectedness.

Signal results stored in columns and rows in the Signal Status Table represent drug-event pairs. Elements include statistics such as EBGM, PRR, ROR, confidence intervals, case counts, and trend data. The highly configurable table includes standard views, options for preferred viewing, and customizable columns that can be adjusted to meet client requirements. Users work with data by filtering results using standard and ad hoc views, visualizing results, and drilling down.

Drug	SOC	Event	Alert	EBGM	PRR	ROR	Case Counts	Comment
Infliximab	Hepat	Granulomatous liver disease	**NEW**	2	22	1.925	32	
Infliximab	Hepat	Cholangitis sclerosing	**NEW**	1	11	1.766	11	Bring to Meeting
Infliximab	Hepat	Autoimmune hepatitis	**NEW**	2	30	1.292	30	
Infliximab	Hepat	Gallbladder perforation	**NEW**	1	2	0.986	5	
Infliximab	Hepat	Cholecystitis	**NEW**	1	22	0.895	32	Pending Further Info
Infliximab	Hepat	Hepatic vein thrombosis	**NEW**	1	3	0.694	3	
Infliximab	Hepat	Cholelithiasis	**NEW**	2	80	0.693	85	
Infliximab	Hepat	Cholelithiasis	**NEW**	1	14	0.672	14	

Figure 3. Signal results are stored in columns in the Signal Status Table. Rows in the table represent drug-event pairs. Users can configure this screen to include information of interest and filter the results using a library of standard and ad hoc views.

Contact Us

For more information about Oracle Health Sciences Empirica Signal, visit oracle.com/healthsciences or call +1.800.ORACLE1 to speak to an Oracle representative.

Oracle is committed to developing practices and products that help protect the environment

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Hardware and Software, Engineered to Work Together