

ORACLE ARGUS PERCEPTIVE

KEY FEATURES

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- Highly configurable search strategies with automated monitoring
- Targeted line of questioning using enhanced data collection forms
- Temporal visualization of date-based case information
- Causality algorithms for uniform and objective assessment
- Automated detection based on rules and statistical algorithm thresholds
- Independent audit trail workflow for risk assessors
- Powerful analytical engines for statistical analysis, alert detection, and case series management
- Case series analysis environment
- Signal analysis report preparation and workup environment
- Management monitoring tools, reports, and escalation environment
- Searchable knowledgebase for signal workups
- Automated data mining engine
- Automated escalation of safety concerns
- Comprehensive audit trail and activity log

Oracle Argus Perceptive, a critical component of the Oracle Argus product family, delivers an integrated solution for proactive pharmacovigilance and risk management. Designed specifically for pharmaceutical risk management, Oracle Argus Perceptive combines with adverse-event-reporting systems to deliver powerful analytics and assessments of drug safety data.

The Signal Detection Challenge

As pharmaceutical companies broaden their focus from transactional case processing to proactive lifecycle risk management, adverse-event-signal detection becomes critical. However, signal detection by itself does not promote adequate risk management. Instead, a structured signal management process is what may ultimately lead to improved risk evaluation, management, and action. Such a process requires a structured methodology for postsignal management.

Oracle Argus Perceptive addresses this problem with a solution that uniquely structures the signal management process to support a company's risk management initiatives. It correlates large and diverse sources of information into useful information for improved signal detection and risk management.

Product Overview

The Oracle Argus product family helps pharmaceutical companies stay in compliance with regulatory requirements in the United States, Europe, and Japan. Oracle Argus Perceptive combines industry-leading adverse-event-report handling with powerful analytical and assessment tools to deliver visualization and real-time analysis; auditable means for signal detection, assessment, management, and documentation; and early risk communication and action planning.

Structured Signal Detection and Alerts

Oracle Argus Perceptive is a fully auditable tool for signal detection, management, early communication, and documentation. By enabling users to identify the most important adverse event reports and integrate them with clinical data, it focuses risk management on the highest-priority events.

Oracle Argus Perceptive also features automated primary and secondary alert detection, an integral part of proactive pharmacovigilance planning. Alerts are fed into a workflow that is completely independent from expedited and periodic report processing. This flexible workflow allows each pharmaceutical company to define its own management pathways that align with its specific risk management program. Intelligent triage and notification features are based on user-defined thresholds. Powerful analytical engines can be used interactively or configured as data mining tools for automatic alerting.

RELATED PRODUCTS

The Oracle Argus product family delivers a comprehensive, Web-based software solution to support the future vision of integrated safety and risk management for the biopharmaceutical industry. With it, health sciences companies can manage the case lifecycle, from entry to reporting and analysis. It is highly configurable to meet the requirements of small to very large customers without customization, and it scales to perform under the most-stringent workloads in global deployments. Oracle's safety reporting and monitoring solutions support holistic, integrated, and proactive risk management strategies and provide better analytics and insight into safety data.

RELATED PRODUCTS

The following products constitute the Oracle Argus product family:

- Oracle Argus Safety
- Oracle Argus Safety Japan
- Oracle Argus Insight
- Oracle Argus Perceptive
- Oracle Argus Affiliate
- Oracle Argus Dossier
- Oracle Argus Interchange
- Oracle Argus Reconciliation
- Oracle Argus Unblinding

Sophisticated Visual Analysis of Pharmacovigilance Data

Oracle Argus Perceptive provides multiple statistical analysis tools. It enables users to define the type of advanced statistical analysis—such as proportional rate ratio (PRR), Chi-square, and 95 percent confidence intervals—required for customized reports and then displays the results graphically. Its powerful analytical and assessment tools provide visualization, real-time analysis, and drill-down analysis.

Comprehensive Knowledge Database

Oracle Argus Perceptive utilizes a comprehensive safety knowledge database to enable good pharmacovigilance process (GPVP) in support of recently released guidance from the International Conference on Harmonisation and the U.S. Food and Drug Administration. Its searchable knowledgebase for signal workup allows for early risk assessment. Automated data mining enables re-evaluation of previously dismissed signals for secondary review and assessment. This central knowledgebase can also contain external data—such as epidemiological studies—as well as case series analysis and signal workup environments. This searchable repository is central for inquiries, periodic safety update report (PSUR) generation, and internal and external risk communication.

Oracle Argus Perceptive's knowledgebase provides a fully auditable environment that frees life science companies to focus on the most-critical events and to view them in the context of all similar reports—within any chosen level of the Medical Dictionary for Regulatory Activities (MedDRA)—in the corporate database for proper assessments as a case series.

Fully Integrated Safety System

Oracle Argus Perceptive seamlessly integrates with Oracle Argus Safety, Oracle Argus Insight, or any adverse-event-reporting system. In addition, it offers integration with multiple statistical engines for analysis, alert detection, and case series management.

Summary

By translating large volumes of data into useful information, Oracle Argus Perceptive improves risk management and signal detection. For many leading companies, Oracle Argus Perceptive has become the tool that serves as the cornerstone of corporate risk management programs.

Contact Us

For more information about Oracle Argus Perceptive, please visit oracle.com 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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