

ORACLE'S ARGUS PERCEPTIVE HELPS LIFE SCIENCE COMPANIES OPTIMIZE THEIR PORTFOLIO BENEFIT:RISK PROFILE



THE ORACLE RISK MANAGEMENT SUITE IS AN ADVANCED SOLUTION THAT ENABLES PRODUCT STEWARDSHIP AND HELPS DRIVE AN ORGANIZATION'S COMPREHENSIVE RISK MANAGEMENT IMPERATIVE, INCLUDING:

- RISK IDENTIFICATION
- RISK ANALYSIS
- RISK MITIGATION
- PORTFOLIO MANAGEMENT

In the CIOMS VIII era, life science companies must holistically address all aspects of risk management and product stewardship, from clinical development through post-marketing. A 360° view includes risk identification, risk analysis, risk mitigation and portfolio management. The Oracle Argus Risk Management Suite helps companies focus on a product's benefit:risk profile while also optimizing the overall portfolio. Oracle's Argus Perceptive is a key component of this solution suite.

Risk Identification

Argus Perceptive helps companies proactively detect safety signals via real-time monitoring of product-event combinations as well as leveraging industry-standard and advanced algorithms for data mining. A complimentary system of primary and secondary alerting, based on therapeutic area and/or safety assessment criteria, supports risk assessors by automating signal detection and identification.

Argus Perceptive gathers data from multiple sources for more accurate signal detection capability. External data and clinical information may also be leveraged to identify additional signals, or to provide a logical context for validation of existing alerts. Recent data can also be used to retrospectively data mine for past correlations.

Traditional qualitative methodologies such as designated medical events (DME) are implemented through the use of primary alert configurations while algorithms are supported via quantitative, secondary alerting. Argus Perceptive offers standard but also innovative algorithms to provide risk assessors with a full spectrum of best practices for identifying potential signals:

Industry-standard and advanced algorithms unique to Argus Perceptive

Proportional Reporting Ratios (PRR)

Chi-Square (χ^2)

95% Confidence Intervals (95% C.I.)

Complete SMQ support

Intra-Product PRR

Case Scoring

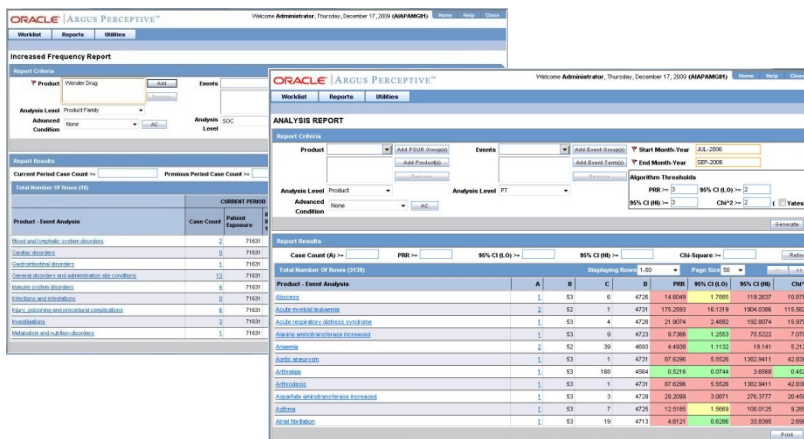
Increased Frequency Reporting based on Patient Exposure

Signal detection, however, is only the first step in assessing a product's risk. Crucial to regulations such as CIOMS VIII, Argus Perceptive provides the framework for a more comprehensive structured signal management process to analyze and mitigate risk, making it a unique and complete solution for managing benefit:risk profiles in the corporate portfolio.

Risk Analysis

Beyond signal detection, Argus Perceptive also provides an integrated platform for risk analysis, enabling real-time analysis as soon as a risk is detected, as well as providing the ability to stratify cases to further understand the public health impact. To ensure regulatory compliance, an integrated environment also supports the tracking of regulatory inquiries for on-going risk management obligations from RMPs and REMS. Advanced features include:

Advanced risk analysis features	
Summary Report	a breakdown of the case series, automatically calculated and included with each triggered alert
Analysis Report	multifaceted report with color-assisted visualization of multiple algorithmic thresholds
Content Matrix	intuitively aids the signal analyst in finding neighboring cases to add to the case series
Increased Frequency Report	Color-differentiated report that is supported by patient exposure data as defined by the FDA increased frequency algorithm



For additional analysis, Argus Perceptive seamlessly integrates with Oracle’s Argus Insight, the business intelligence and analytics tool for pharmacovigilance. Argus Insight provides the risk assessor with powerful querying capabilities, a predefined library of multidimensional reports, user-friendly ad hoc report creation, and audited case series updating and freezing functionality. With a single click, case series can be passed from Argus Perceptive to Argus Insight and vice versa, providing the ultimate analytic flexibility.

Risk Mitigation

Confirmed risks must be addressed within company SOPs to support REMS and RMP requirements. Argus Perceptive offers a structured approach for risk mitigation, ensuring adherence to the company pre-defined SOP for triage, assessment, mitigation and follow-up. This includes features such as flexible and fully configurable workflows, including group worklists, workflow rules, due dates and action items. Actions resulting from a confirmed signal are tracked and documented in a collaborative environment, while risk assessors may also schedule reports and queries to

CONSULTING SERVICES

Oracle offers a complete suite of consulting and training services that help customers implement and become productive with Argus Perceptive as quickly as possible.

ORACLE'S ARGUS PERCEPTIVE TECHNICAL SPECIFICATIONS

- Web server: Windows 2003 SP2 Standard & Enterprise
- Database server: Windows 2003 SP2 Standard & Enterprise, Red Hat Linux 5.0
- Oracle server: Oracle Standard & Enterprise 10.2.0.4, 11.1.0.7
- Client: XP Pro SP3 / Vista SP1 all versions

ensure timely assessments. Argus Perceptive thereby enables a continuous process of assessment and mitigation based on a product's identified risk.

Argus Perceptive can store the company's global Signal Workup Document template so that the latest version is instantly and centrally available to signal analysts. Check-out and check-in as well as version history is supported by the application. The final Signal Workup Document is stored together with the triggered alert so that all relevant information is in one place.

Through the process of archiving both confirmed signals and alerts evaluated as non-risks for the time being, risk assessors build an invaluable knowledgebase in Argus Perceptive over time. The application can be configured to continue monitoring for new cases that can awaken latent, archived alerts in the knowledgebase and give analysts the opportunity to reevaluate the situation. Additionally a watchlist with reminder functionality keeps important alerts on the radar screen.

Management gains visibility into risk metrics for each product via executive dashboards, providing the ability to make safety-based portfolio decisions. Importantly, Argus Perceptive also enables companies to rapidly respond to regulatory inquiries, helping to ease the burden of compliance.

Argus Perceptive, in conjunction with Argus Insight and Oracle's Argus Dossier, allows companies to manage the benefit:risk profile across their entire product portfolio. Oracle's risk management solutions thus help life science companies move beyond mere regulatory compliance to focus on holistic product stewardship.

Contact Us

For more information about Oracle Argus Perceptive, please visit the [Oracle Health Sciences applications website](#) or call +1.800.ORACLE1 to speak with an Oracle representative.

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