# 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
- Busine Alvana Visuali.
- 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 realtime 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. Argas 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')
95% Confidence Intervals (95% C.L.)
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. Cracial 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.



# **Oracle Argus Documentation**

**M** Tight



Unveiling the Power of Verbal Artistry: An Psychological Sojourn through **Oracle Argus Documentation** 

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