

# 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 ( $\chi^2$ )                                              |
| 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.

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**Brendan G. Carr**



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