Oracle Argus Safety

Market-leading pharmacovigilance solution for automated adverse event case processing, global regulatory reporting, and safety signal management.

https://www.oracle.com/life-sciences/safety-solutions/

Overview

Oracle Argus Safety is a comprehensive, industry-proven pharmacovigilance platform designed for life sciences companies, including pharmaceutical manufacturers, sponsors, and Contract Research Organizations (CROs). It is widely considered the gold standard for drug safety management, supporting both pre-market (clinical trials) and post-market surveillance for drugs, biologics, vaccines, devices, and combination products.

Key Benefits and Capabilities:

Workflow Automation: Features for intake, case prioritization, field validations, coding, narrative generation, and regulatory submission can reduce manual work by 50% or more, maximizing case processing efficiency.
Global Regulatory Compliance: The system is continuously updated to ensure compliance with a wide range of global regulations and standards, including ICH E2B (R3), E2B (R2), PMDA, FDA (eVAERS, eMDR), and IDMP.
End-to-End Case Management: It provides a central, secure platform for documenting all adverse event data, including source documents, follow-up information, medical coding (MedDRA, WHO Drug), medical assessments, and regulatory reports.
Safety Analytics: Argus Advanced Cloud includes Oracle Analytics, an AI-powered solution that provides deep insights into safety data, workflow metrics, and submission compliance to facilitate faster, informed decision-making and proactive risk management.
Scalability: The platform is highly scalable, designed to handle millions of safety cases annually and support the needs of companies ranging from small organizations to large global enterprises.
Target Users & Use Cases:

Drug Safety/Pharmacovigilance teams
Regulatory Affairs professionals
Medical Reviewers
Quality Assurance teams
CROs managing safety data for clients
The primary use case is to streamline and automate the entire drug safety lifecycle, ensuring timely and accurate regulatory adherence while enabling proactive signal detection.

Key Features

- Adverse Event Case Processing and Management
- Global Regulatory Reporting (ICH E2B, PMDA, FDA)
- Workflow Automation and Conditional Touchless Processing
- Safety Signal Detection and Risk Management
- Medical Coding (MedDRA, WHO Drug)
- Safety Analytics and Business Intelligence Dashboards
- Clinical-to-Safety Reconciliation
- Document Management Integration

Pricing

Model: enterprise

Enterprise-level subscription pricing is not publicly disclosed and requires direct consultation with Oracle Sales. It is typically licensed based on usage, modules, and number of users.

Target Company Size: medium, enterprise

Integrations

Oracle Argus Insight, Oracle Empirica Signal (Signal Detection), Clinical Trial Solutions (e.g., Oracle Clinical), Safety Case Intake Systems, Document Management Systems (e.g., Documentum), Single Sign-On (SSO) Providers (e.g., PingFederate)

Compliance & Certifications

ICH E2B (R3), FDA 21 CFR Part 11, EU Annex 11, GDPR (Data Privacy Methodologies), PMDA Standards, IDMP