Detect Risks Earlier, Reduce Costs, and Increase Compliance with Unified Multivigilance

SAFETY CLOUD AT A GLANCE

- #1 safety case management and #1 safety signal management integrated solutions mean less risk for customers
- Over 30 companies use Oracle Argus Safety Japan for compliance with PMDA requirements
- Efficiency gains up to 51% with workflow automation and optimization by Oracle Health Sciences Consulting
- Customer support for both cloud and on-premise deployments is available all day every day
- Integration with Oracle Health Sciences InForm increases productivity and speeds clinical SAE reporting

3 out of 5 companies in the Top 100 Pharma use Oracle Health Sciences Safety Suite applications

3/5

24x7

DETECT EARLY

- Empower users with business intelligence for scientific analysis and operational metrics using Oracle Argus Enterprise Edition
- Detect and analyze safety signals in trial data during clinical development with Oracle Health Sciences Empirica Study
- Detect and analyze safety signals in post-marketing spontaneous adverse reaction data with Oracle Health Sciences Empirica Signal
- Manage signals with Oracle Health Sciences Empirica Topics to avoid recalls, lawsuits, regulatory penalties, and inspection findings

REDUCE COST

- Configure an extensible and flexible solution instead of creating costly customizations
- Automate business processes and workflows using artificial intelligence to increase efficiency and productivity
- Take advantage of out-of-the-box integrations to avoid building new interfaces from scratch
- Use Oracle Cloud to lower total cost of ownership, increase security, and accelerate implementations and upgrades

INCREASE COMPLIANCE

- Meet regulatory requirements for E2B(R3), eVAERS, eMDR, and IDMP with Oracle Argus Standard Edition
- Comply with PMDA guidelines for expedited and periodic reporting with Oracle Argus Safety Japan
- Track current and retrospective compliance of workflow steps and submissions with Oracle Argus Enterprise Edition
- Fulfill EU GVP Module IX and CIOMS VIII requirements with Oracle Health Sciences Empirica Topics

BROADEST PLATFORM

The Oracle Health Sciences Safety Cloud offers the industry’s broadest platform of integrated systems and workflows to drive greater compliance and data insight while reducing cost

Case Intake & Data Entry
Medical & Product Coding
Quality Review & Medical Assessment
Expedited & Periodic Reporting
Business Analytics & Intelligence

Signal Detection & Analysis
Clinical & Spontaneous Data Mining
Signal Workflow & Tracking
Lifecycle Signal Management
Benefit-Risk Management

Oracle Health Sciences Safety Cloud

Oracle Health Sciences Safety Cloud

An integrated suite of the market-leading safety case management and safety signal management solutions, enabling unified multivigilance.
For more information visit www.oracle.com/goto/safety

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Oracle Health Sciences Safety Cloud

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