

Enable Compliance, Quality, and Efficiency in Your Safety Operations with Oracle Argus

A Complete Solution for Clinical and Post-Marketing Safety

A constantly evolving regulatory climate worldwide, the critical focus on understanding the risk/benefit profile of products through all phases of development, increasingly complex and global clinical trials, and shrinking R&D resources have all fueled new demands for more efficient and effective pharmacovigilance solutions to protect patients and manufacturers against risk.

Oracle Argus is a comprehensive pharmacovigilance platform which enables manufacturers to make faster and better safety decisions, optimize global compliance, and easily integrate risk management. Unlike solutions that require heavy customization, Oracle Argus provides deep and integrated safety functionality out of the box that scales to millions of cases and easily aligns with your safety and business processes.

The software enables a highly scalable end-to-end safety process providing automated global case processing, periodic reporting, E2B intake and submission, comprehensive reporting, detailed analytics, and Japanese safety operations from within a single system.

| Capability | Cloud Standard | Cloud Enterprise | On-Premise Standard | On-Premise Enterprise | Argus Japan |
|--|----------------|------------------|---------------------|-----------------------|-------------|
| Single global database | ■ | ■ | ■ | ■ | ■ |
| Case processing | ■ | ■ | ■ | ■ | ■ |
| Case processing – partners | ■ | ■ | ■ | ■ | ■ |
| E2B compliance | ■ | ■ | ■ | ■ | ■ |
| Periodic submissions | ■ | ■ | ■ | ■ | ■ |
| Advanced querying and reporting | | ■ | | ■ | |
| Visibility of KPIs and case processing metrics | | ■ | | ■ | |
| Data model for signal detection on Argus AEs | | ■ | | ■ | |
| Automated unblinding | | | ■ | ■ | |

Oracle Argus offers complete, purpose-built safety capabilities out-of-the-box, with flexibility to choose the capabilities that best fit your organization's needs today and to plan for future growth.

KEY BENEFITS

- Improve global compliance
- Increase efficiency of safety operations
- Enhance case quality
- Make faster, more informed safety decisions
- Scale easily to millions of cases
- Readily configure software to your business processes

KEY FEATURES

- Integrated, highly scalable end-to-end safety platform
- Single global database including Japan
- Common code base
- Regular release schedule
- Automated global case processing
- Periodic reporting
- E2B exchange
- Scientific querying
- Detailed analytics
- Out-of-the-box integration with Oracle Health Sciences InForm EDC Suite

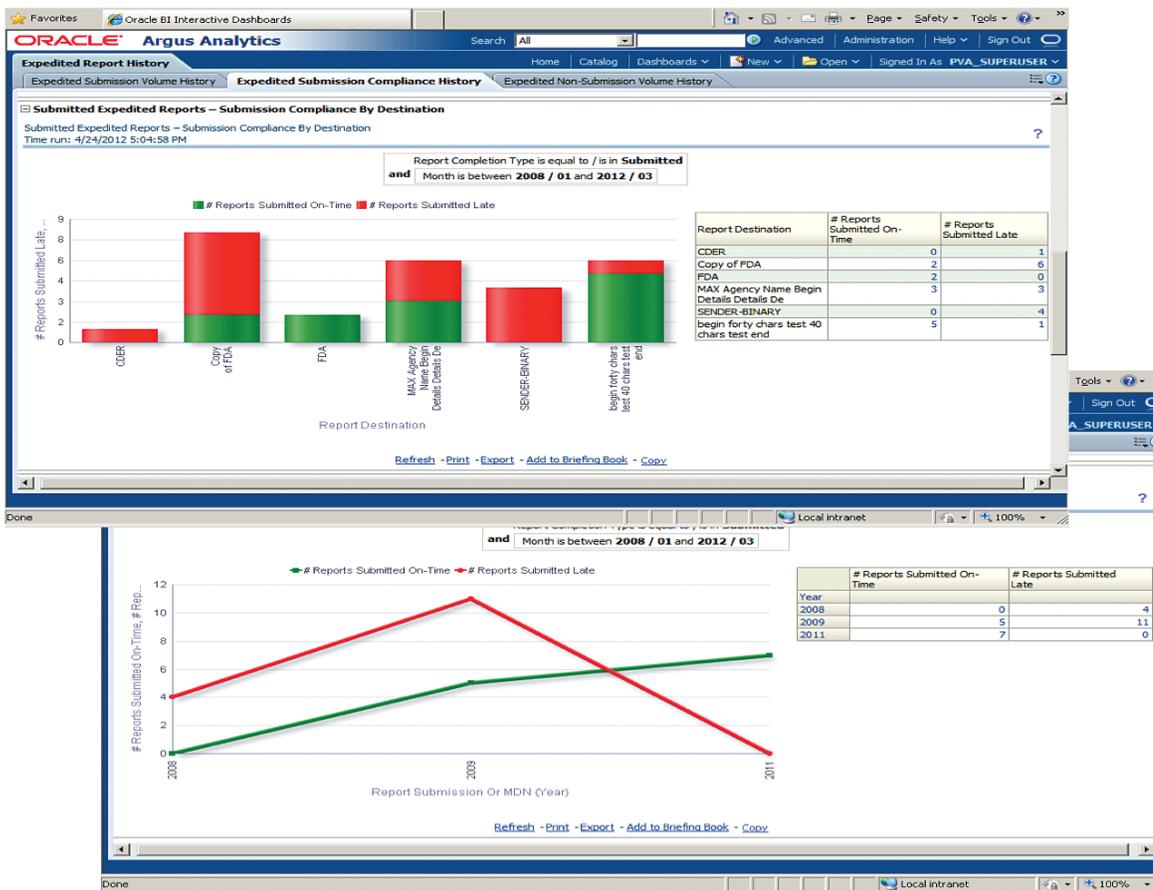
Make Faster, Better Safety and Risk Management Decisions

Oracle Argus provides comprehensive reporting, advanced analytics, and scientific querying for all levels of user ability to help you make fact-based safety decisions quickly.

- Argus self-service querying provides visibility to key safety data to set and manage risk-benefit ratios, letting you make timely, science based decisions on end-to-end safety and risk management.
- On-demand reporting provides detailed case information in minutes, letting you quickly and effectively prepare for and respond to regulatory information requests and audits.
- Real-time metrics measuring work in progress let you see current workload and resource utilization to make faster, better decisions on workload rebalancing before cases and reports become late.
- Trailing metrics measuring completed work provide visibility to volumes and trends over previous periods to quickly identify underperforming areas for additional training, staff augmentation, or process changes.
- Advanced scientific business intelligence offers efficient querying, drill-down analysis, and report generation with no impact on transactional performance so you can perform key analyses quickly and confidently.
- Argus utilizes built-in and configurable industry best practices that walk users through all required information for a case including internal deadlines, reducing the risk of missing data or cases entered late.

The screenshot displays the Oracle Argus Insight web application. At the top, it shows the user 'jonathanh' on 'Wednesday January 27, 2010'. Below the navigation bar, there's a 'CASE SERIES LIBRARY' section with search filters for Name, Description, Last Modified, User Full Name, Category, Source, and Cases. A table lists case series with columns for Name, Description, Last Modified, User Full Name, Category, Source, and Cases. Below this, a 'Report1' section shows a detailed table of cases with columns for Case Number, Age, Sex, Source, Country, Case, Medical Name, Product, Dose, Frequency, Date of Onset, Reported, and Reported on. The table contains several rows of case data, including details for 'ENT5_907-003' and 'ENT5_907-004'.

Oracle Argus offers scientific querying, reporting and business intelligence through a safety data mart, including ad hoc and standard line listings and summary tabulations and an easy-to-understand end-user query interface. You can freeze and merge case series, add and remove cases, and share case series for directed research.



Oracle Argus offers operational metrics, KPIs and business analytics to improve efficiency, quality, and compliance. Retrospective KPIs summarize past performance, while current case activity can be monitored in real time.

Ensure Compliance with Regulatory Agencies in Every Region

Oracle Health Sciences safety experts track regulatory developments worldwide to keep our safety products and your organization current with constantly evolving regulations.

- Oracle safety product strategists sit on both ICH and HL7 working groups and work closely with the FDA, EMA, and PMDA to keep products current and help you easily adapt processes to new regulatory requirements.
- Argus Mart transforms Argus safety data for optimized data mining by Empirica Signal to enable more holistic risk management by automating and standardizing signal detection of in-house safety data.
- Support for import, export, and tracking of ICSRs via the E2B standard helps ensure cases are reported instantly and accurately.
- Comprehensive, collaborative and user-friendly periodic AE reporting encompassing PSUR, ASR, DSUR, PADER and more reduces the time required to produce periodic submissions while increasing their accuracy.

"We aim to use gold-standard products in the pharmaceutical industry. With Oracle Health Sciences Empirica Signal and Oracle Argus Safety, we have achieved the patient-safety level that is so important to us as a research-based pharmaceutical."

– Dr. Marc A. Zittartz, Grünenthal GmbH





Oracle Argus provides a true single global safety database that supports operations in all regions including Japan, with no synchronization or separate transmission of data required, increasing the accuracy and consistency of your global safety operations, processes, and data.

Increase the Accuracy and Consistency of your Safety Data Worldwide

Oracle Argus gives you a single global database and advanced analytics that improve data accuracy while giving your safety analysts more time to review cases.

- Oracle Argus provides a true single global safety database that supports operations in all regions including Japan, with no synchronization or separate transmission of data required, increasing the accuracy and consistency of your global safety operations, processes, and data.
- Argus offers comprehensive, retrospective and real-time analytics for workflow state, case lock, and expedited report submission compliance to improve the quality and timeliness of safety case processing and reporting while reducing operational risks for both post-marketed and clinical trial pharmacovigilance data.
- Partner case processing provides a single interface and repository for safety cases processed by affiliates, eliminating duplicate data entry and the risk of conflicting case data.

Optimize Efficiency and Effectively Manage Growing Case Volume and Complexity

Oracle Argus provides flexible configuration, automated case processing, and integrated functionality to increase the productivity and efficiency of your safety operations.

- Argus readily configures to your own processes without customization so you can incorporate safety planning into your corporate strategy to increase efficiency as well as case and reporting compliance.
- The software delivers a flexible, automated case processing workflow with configurable dynamic timelines, worklist management, and company-defined reporting rules to optimize case processing efficiency and effectively manage increasing volumes and complexity of safety cases.
- Argus provides comprehensive case series management functionality such as the annotation of cases within a case series and merging of two case series into one for scientific analysis.
- Fully integrated functionality through a single login with an intuitive menu structure and visual cues means you have a consistent user experience, improving time-to-value for the system and accelerating safety processes.
- Integration with the Oracle Health Sciences InForm EDC Suite lets you transfer time-critical SAE data from InForm to Argus within minutes of entry in InForm, reducing or eliminating the need for SAE data reconciliation to save time and increase accuracy.
- Argus offers comprehensive, context-sensitive inline help as well as 24/7 global help desk support by Oracle employees so you increase productivity and reduce business disruption and downtime.

Choose Safety Software with Proven Performance, Reliability, and Scalability

Oracle Argus delivers a safety application, system, database, and hardware architecture and components built on leading Oracle technology.

- Argus features a highly robust and scalable architecture built on leading Oracle technology and optimized for maximum performance, scalability, and security so your data is reliable and secure whether you're managing dozens or hundreds of thousands of cases per year.
- The Oracle Health Sciences well-established Software Development Life Cycle (SDLC) provides a rigorous and proven process that includes dedicated product strategists, domain experts, software engineers, audit and compliance, QA and more to ensure product performance, reliability, and security.
- Oracle Argus provides a stable, common code base among all customers, enabling fast, reliable and cost-effective updates and upgrades, as well as higher-quality support to increase compliance and productivity while reducing the risk of downtime and disruption.

"In the future, I will seek Oracle support as the business grows and BSC safety needs change."

– Lou Poirier,
Senior Manager
IS Clinical,
Boston Scientific

You Can Rely on Oracle as your Partner for Safety Technology Today and in the Future

Oracle Health Sciences provides the vision, innovation, and resources to be your proven, long-term partner in safety technology supporting your business objectives.

- Oracle Health Sciences implements a well-defined, customer and industry-driven strategy to improve safety compliance and efficiency through aggressive product innovation and integration, assuring you of a product roadmap with expanding safety and risk management capabilities.
- The broad and deep Oracle Health Sciences Safety Suite provides access to best-of-breed Empirica signal detection products integrated with Argus as well as rapid expandability to support extended business operations beyond safety to help future-proof your investment in safety technology while lowering costs.
- Major releases of Oracle Argus occur every 12-18 months and minor releases more frequently, backwards-compatible – letting you obtain the benefit of continuous product innovation and regulatory updates.
- Oracle Argus is backed by the resources of a Global 500 company, enabling an unmatched investment in life sciences products, services, and support so your company benefits from ongoing product innovation and global support with reduced risk of business disruption.

Why Oracle Health Sciences

Backed by the resources of a Global 500 company, Oracle Health Sciences provides you with the industry's most comprehensive set of software solutions addressing every aspect of the health value chain from discovery to care delivery. With thousands of professionals in offices throughout North America, EMEA, and Asia, Oracle Health Sciences offers unmatched resources to enable your organization's goals today and in the future.

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