

ORACLE ARGUS SAFETY

KEY FEATURES AND BENEFITS

FEATURES

- Electronic submission manager
- Signal generation, crisis management, and configurable workflow
- Intuitive graphical interface
- Affiliate support module
- Automated report scheduling
- Reconciliation with clinical systems
- Compliance and productivity dashboards
- Autonarratives and letter generation
- MedDRA browser with full hierarchy, compliant with current MedDRA versions
- 21 CFR Part 11 compliance
- ICH:E2B electronic data submission
- ICH:E2C periodic safety update report (PSUR)
- ICH clinical trial periodic report and EUSAR
- IND and NDA periodic report
- CIOMS II line listing and CIOMS V
- EMEA/CPMP reporting
- Integrations with dsNavigator, Oracle Thesaurus Management System, and WHO drug dictionary

BENEFITS

- Collects, monitors, and analyzes safety data across clinical trials, postmarket surveillance, and patient care
- Provides a complete and integrated view of reported adverse events, clinical studies, and medical data
- Identifies risks early for lower clinical development costs
- Expedites reporting for drugs, devices, and vaccines
- Enables early detection of pre- and postmarket safety issues

Oracle Argus Safety—the industry’s leading Web-based, off-the-shelf system for pharmacovigilance—provides a comprehensive foundation for case management and reporting. It helps you manage data from multiple sources, meet strict global compliance guidelines, and access a flexible drug safety database. As part of a fully integrated safety system, it offers scalability and high performance for even the largest enterprises. With Oracle Argus Safety, you can improve drug safety by implementing a comprehensive software solution that enables integrated safety and risk management.

The Pharmacovigilance Challenge

Bringing a new drug, device, or therapy to market has always been a complicated process involving corporations, government, laboratories, doctors, and patients. However, in recent years, the volume and complexity of clinical trials required to prove efficacy and safety are increasing. With more parties managing research, these additional sources of data have made the collection and analysis of safety data more complex. In addition, new regulations and government initiatives are increasing the focus on safety and pharmacovigilance. Because safety and responsibility have always been hallmarks of the industry, health science companies have increased investments in software that provides greater transparency into drug safety.

Identifying safety issues earlier in the development process is critical to reducing the costs and risks associated with bringing drugs and devices to market. Sponsors, contract—or clinical—research organizations (CROs), trial sites, regulatory agencies, and medical institutions—all of which use disparate systems—are responsible for managing data. An integrated system for supporting safety and risk management during early development, market introduction, and postmarket surveillance is required.

Product Overview

Oracle Argus Safety is such an integrated system. It provides the most comprehensive case data management and regulatory reporting in the pharmaceutical industry. Leading pharmaceutical companies use Oracle Argus Safety to provide complete global regulatory compliance, adverse events management, streamlined electronic business process workflow, and data exchange within a scalable, high-performing, and cost-effective architecture.

With Oracle Argus Safety, companies realize productivity gains through streamlined business processes. For example, rapid deployment is enabled via an integrated flexible workflow engine that can be configured in the user interface. The built-in

MedDRA browser allows for full autoencoding capability. In addition, Oracle Argus Safety can integrate with central coding applications via an Oracle Argus API.

Global Regulatory Reporting

Oracle Argus Safety provides a rich native integrated querying and reporting environment for unified regulatory and management reporting. Global annual safety reports for clinical and postmarketing surveillance are automatically generated. Case quality is managed through logical quality control checks as well as full source document integration. In addition, Oracle Argus Safety complies with all major regulatory reporting guidelines—including those from the European Medicines Agency (EMA), the U.S. Federal Drug Administration (FDA), and Japan's Pharmaceutical and Medical Devices Agency (PMDA). Oracle's proactive approach to monitoring global guidances ensures consistent regulatory compliance.

Oracle Argus Safety is fully compliant with the International Conference on Harmonisation's guidelines for transmitting data elements in individual case safety reports (ICH:E2B), enabling your company to electronically exchange information with partners and regulators. Finally, Oracle Argus Safety enables your product to be reported as a drug in one market and as a device or a vaccine in another market—based on how a product is interpreted by local regulatory authorities.

Flexible Drug Safety Database and Drug Dictionary Access

Oracle Argus Safety is a single global database allowing instant availability of a case, regardless of where in the world the case originated. The steps involved in processing individual case reports can be configured to match any unique business process—whether centralized or decentralized. Oracle Argus Safety's ability to support any global workflow model makes it the comprehensive pharmacovigilance solution.

In addition, Oracle Argus Safety fully supports all standard dictionaries, including

- Medical Dictionary for Regulatory Activities (MedDRA)
- Coding Symbols for a Thesaurus of Adverse Reaction Terms (CoSTART)
- World Health Organization Adverse Reactions Terminology (WHO-ART)
- World Health Organization Drug Dictionary (WHO-DRUG)
- International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)

Scalability and High Performance

Oracle Argus Safety is a proven fourth-generation, Web-based system used by the most-demanding and largest pharmaceutical companies. As a commercial, off-the-shelf, Web-based system, it eliminates the risk and expense associated with custom-built safety solutions and frees your IT resources to focus on more-strategic projects. This centralized and easy-to-use system delivers simplified rollout and deployment, low long-term maintenance costs, and effortless upgrades.

RELATED PRODUCTS

The Oracle Argus product family delivers a comprehensive, Web-based software solution to support the future vision of integrated safety and risk management for the biopharmaceutical industry. With it, health sciences companies can manage the case lifecycle, from entry to reporting and analysis. It is highly configurable to meet the requirements of small to very large customers without customization, and it scales to perform under the most-stringent workloads in global deployments. Oracle's safety reporting and monitoring solutions support holistic, integrated, and proactive risk management strategies and provide better analytics and insight into safety data.

RELATED PRODUCTS

The following products constitute the Oracle Argus product family:

- Oracle Argus Safety
- Oracle Argus Safety Japan
- Oracle Argus Insight
- Oracle Argus Perceptive
- Oracle Argus Affiliate
- Oracle Argus Dossier
- Oracle Argus Interchange
- Oracle Argus Reconciliation
- Oracle Argus Unblinding

Fully Integrated Safety System

Oracle Argus Safety seamlessly integrates with other products within the Oracle Argus product family, so pharmaceutical companies have the option of adding further functionality. The following products can be integrated with Oracle Argus Safety:

- Oracle Argus Insight and Oracle Argus Perceptive, which deliver powerful risk management analysis tools to ensure comprehensive product stewardship
- Oracle Argus Interchange, which enables electronic exchange with partners and regulators to meet demanding global safety regulations and to integrate with partners
- Oracle Argus Affiliate, which integrates affiliates and remote sites into the global workflow
- Oracle Argus Safety Japan, which provides a full Japanese interface to each function in Oracle Argus Safety and includes specific compliance capabilities
- Oracle Argus Dossier, which provides a collaboration platform to support the document writing process for periodic reports
- Oracle Argus Reconciliation, which enables efficient reconciliation of data between clinical data systems and Oracle Argus Safety

Summary

Oracle Argus Safety is the most widely used drug safety system in the world, employed by small and large pharmaceutical companies alike. It provides businesses with the peace of mind of knowing that drug safety data is being properly managed and will always comply with global regulations.

Contact Us

For more information about Oracle Argus Safety, please visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.



Oracle is committed to developing practices and products that help protect the environment

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