

ORACLE ARGUS INTERCHANGE

KEY FEATURES AND BENEFITS

FEATURES

- Graphical display that presents transmission status
- Compliance with ICH:E2B and CDISC:ODM standards
- Integration with Oracle Argus Safety
- Immediate case triage upon receipt of electronic data

BENEFITS

- Delivers rapid ROI
- Eliminates data entry redundancy and errors associated with manual data input
- Allows timely information sharing with partners and agencies worldwide

Oracle Argus Interchange is the electronic submission and exchange component of the Oracle Argus product family. It allows pharmaceutical companies to share important drug safety information with partners in accordance with regulatory guidelines.

The Data Exchange Challenge

In pursuit of drug safety, pharmaceutical companies share information and data with licensing partners, clinical research organizations, laboratories, and hospitals. In addition, case safety reports are submitted to regulatory agencies including the European Medicines Agency (EMA), the U.S. Federal Drug Administration (FDA), and Japan's Pharmaceutical and Medical Devices Agency (PMDA). So much data is shared that the International Conference on Harmonisation has published guidelines (ICH:E2B) for electronic data exchange that guard patient privacy and ensure that the necessary information is included in the transmission.

Product Overview

Oracle Argus Interchange allows for secure, electronic exchange of drug safety information. Transmission of required data elements from case safety reports is done in accordance with ICH:E2B guidelines.

Electronic Exchange with Partners and Regulators

Oracle Argus Interchange enables pharmaceutical companies to exchange vital drug safety information with regulators and partners worldwide. Cases are reported instantly and accurately using standardized, global reporting and transmission processes. A color-coded graphical display delivers real-time insight into transmission status. Pharmaceutical companies can immediately triage cases upon electronic intake of data using a selective intake process. Importantly, Oracle Argus Interchange is seamlessly integrated with Oracle Argus Safety to facilitate the import, export, and transmission of case safety reports.

Link for Preclinical and Post-Marketing Safety Information

Oracle Argus Interchange provides the critical link for connecting the preclinical and post-marketing domains. This crucial component allows communication between pharmaceutical companies' e-clinical and safety systems and delivers immediate return on investment. Oracle Argus Interchange will allow any standards-based systems—from those based on the ICH:E2B electronic reporting format to those using the Clinical Data Interchange Standards Consortium's operational data modeling (CDISC:ODM)—to instantly exchange adverse events data. It thereby eliminates costly data entry redundancy and any possibility of introducing errors.

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 Interchange provides the unique ability to configure the business rules for transmission and import profiles. The graphical display tracks individual case summary reports (ICSRs) to meet service level agreements for regulators and trading partners. In addition, selective intake for the acceptance of initial and follow-up ICSRs increases business and IT productivity. Seamless integration with Oracle Argus Safety allows users to create and update cases eliminating duplicate data entry and reducing case processing times.

Contact Us

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



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