

ORACLE ARGUS AFFILIATE

KEY FEATURES AND BENEFITS

FEATURES

- Origination of cases via case entry screens
- Tracking of local data items
- Support for e-signatures
- Duplicate search capabilities
- Local labeling decisions made against local data sheet or license
- Case views provided to appropriate local affiliate
- Ability for several affiliates to simultaneously view and make local labeling calls against the same locked case
- Views of core documents and global protocols such as action items on a work list
- Central staging area for reviewing submitted affiliate cases
- Electronic submission capabilities
- Querying and reporting of cases received and submitted
- Audit trails

BENEFITS

- Improve data safety with a single case management database
- Realize immediate ROI by streamlining and integrating affiliate business processes
- Increase worker productivity by eliminating redundant data entry
- Reduce risk by allowing central safety group to accept or reject affiliate cases

Oracle Argus Affiliate works in conjunction with Oracle Argus Safety to provide pharmaceutical and medical device companies with an effective way to integrate business processes with contract research organizations and other affiliates. With Oracle Argus Affiliate, you can improve worker productivity by reducing duplicate tasks and improve data safety by managing a single case database.

The Affiliate Challenge

Bringing a new drug, device, or therapy to market has always been a complicated process involving multiple parties. However, in recent years, the number of participants in clinical trials has increased. The contract—or clinical—research organization (CRO) industry has developed as pharmaceutical research-and-development efforts have become more complex. As the pharmaceutical industry concentrates resources on core skills, CROs and affiliate organizations help with many of the processes involved in bringing new compounds and devices to market. All of these affiliate organizations are responsible for managing data, and all of them use disparate systems. However, with Oracle Argus Affiliate, you can integrate all affiliate sites into the global case workflow.

Product Overview

Oracle Argus Affiliate provides true integration of affiliate sites into your business processes for case management and reporting. Affiliate sites are responsible for local cases, but the central safety group at the contracting organization maintains overall visibility and control. Because Oracle Argus Affiliate eliminates manual processes, companies immediately see results in the form of increased worker productivity. Finally, it integrates easily with Oracle Argus Safety, a comprehensive foundation for case management and reporting.

Local Processing with Central Visibility

Oracle Argus Affiliate allows case data entry at the source to minimize mistakes from dual entry. It provides a complete case review, acceptance of the case into the central database, and determination of whether a case is reportable—all at the local level. Affiliate sites receive only cases that are specific to the local site, and users manage and track only the cases specific to their workflow. The central safety department retains full visibility into all affiliate sites and decisions through a single case database.

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

Productivity Improvement

Oracle Argus Affiliate delivers immediate return on investment, by eliminating redundant data entry, streamlining paper-based processes, and eliminating the need for fax or e-mail communications. This Web-based module utilizes Oracle Argus Safety's central database and does not require additional resources to maintain the system.

Full Integration with Oracle Argus Safety

Oracle Argus Affiliate works in tandem with Oracle Argus Safety to seamlessly integrate local affiliate sites into the worldwide safety workflow via a single case database. The central safety department retains control of the environment and the ability to provide restricted access. It therefore also provides a convenient way to integrate CROs into the safety reporting process.

Contact Us

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



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