

# SUPPORTING DRUG SAFETY AND REGULATORY COMPLIANCE WITH ORACLE'S ARGUS SAFETY



ORACLE'S ARGUS SAFETY IS A COMPREHENSIVE PHARMACOVIGILANCE PLATFORM DESIGNED TO ENABLE LIFE SCIENCES COMPANIES TO FOCUS ON PRODUCT SAFETY AND COMPLIANCE.

WITH ARGUS SAFETY, COMPANIES CAN:

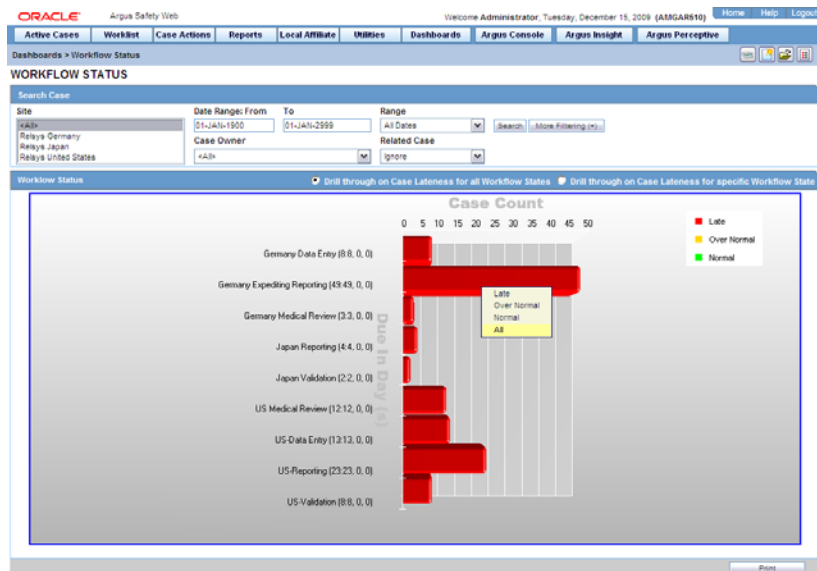
- ENSURE GLOBAL REGULATORY COMPLIANCE
- MAKE FASTER, SCIENCE-BASED SAFETY DECISIONS
- INTEGRATE SAFETY AND RISK MANAGEMENT
- LOWER THE COST OF PHARMACOVIGILANCE

Companies are increasingly shifting their focus to a more holistic view of product safety beginning in clinical development and continuing through post-market surveillance. Oracle's Argus Safety is a comprehensive platform designed specifically to address the life sciences industry's complex pharmacovigilance requirements. Argus Safety's advanced database helps ensure global regulatory compliance, enables sound safety decisions and integrates safety and risk management functions.

## Ensuring Global Regulatory Compliance

Life sciences organizations must ensure that they are compliant with global regulations and guidance, including those of EMA, FDA, ICH, and a myriad of national authorities. Extensive license partnerships, as well as outsourcing of some functions, complicate this scenario and the industry is finding it increasingly challenging to manage its world-wide reporting obligations. Companies depend on Argus Safety to help manage their regulatory compliance requirements in a timely and proactive manner.

Managers and executives can obtain visibility into reporting metrics and compliance by leveraging Argus Safety's advanced reportability functionalities, such as comprehensive dashboards and metrics. In addition, Argus Safety's flexible configuration can model virtually any business process, supporting case management and reporting compliance internally as well as across license partner networks.



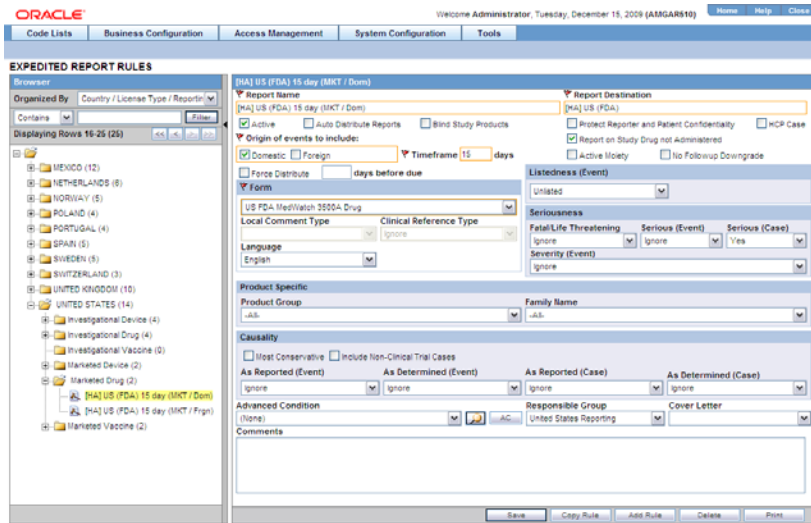
Argus Safety supports reporting compliance via a comprehensive and robust reporting engine that allows users to configure specific rules to match regulatory requirements. When combined with advanced automation

features such as "Auto/Force Distribute" and "Auto-Submit", it enables full compliance and can lower the cost of regulatory reporting.

**Better Insight Into Safety Data for Faster Decision-Making**

Argus Safety has been developed with input from leading life sciences companies and industry thought leaders with a focus on efficient and effective safety management.

The system is designed for fast safety data entry. Advanced functionality such as dynamic workflows, worklist management, company-defined reporting rules and extensive automation are incorporated to ensure maximum case processing efficiency.



The system can be easily queried by end users without requiring SQL or the support of IT departments. Thus, safety data is readily accessible for timely review and reporting. Other modules can also be fully integrated with Argus Safety, providing the ability to readily reconcile SAEs from clinical trials or efficiently manage periodic reports.

INTERACTIVE RECONCILIATION REPORT

Total Number of Rows (41) Show Discrepancies Only Clear filters Displaying Rows 101-200 Page Size 100

Unmatched Records	Date	Status	Study #	Inv ID	Pat ID	Inst.	Death Date	SAE ID	SAE ID Suffix	Verbatim	LLT	Start	Stop	Intensity	Treatment	Outcome	Causality
2000US 00001		Resolved	WONDER 00123	1234567	11223344	AKA	N/A										
Argus-01	20-APR-2008	Resolved	WONDER 00123	1234567	11223344	AKA		1234 567		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
CDMS-01	20-APR-2008	Resolved	WONDER 00123	1234567	11223344	AKA		1234 567		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
Argus-02	20-APR-2008	Pending	WONDER 00123	1234567	11223344	AKA		1234 567		Fever	10016560	04-NOV-2005	04-NOV-2005	Mild	No	Recovered	Probably
CDMS-02	20-APR-2008	Pending	WONDER 00123	1234567	11223344	AKA		1234 567		Fever	10016560	04-NOV-2005	04-NOV-2005	Mild	No	Recovered	Probably
2000US 00002		Pending	WONDER 00123	1234567	11223344	AKA	N/A										
Argus-01	20-APR-2008	Pending	WONDER 00123	1234567	11223344	JHW		1234 568		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
CDMS-01	20-APR-2008	Pending	WONDER 00123	1234567	11223344	JHW		1234 568		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
2000US 00002		Pending	WONDER 00123	1234567	11223344	AKA	N/A										
Argus-01	20-APR-2008	Accepted	WONDER 00123	1234567	11223345	ARR		1234 568		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Moderate	Yes	Recovered	Probably
CDMS-01	20-APR-2008	Accepted	WONDER 00123	1234567	11223345	ARR		1234 568		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Severe	Yes	Recovered	Probably
Argus-02	20-APR-2008	Pending	WONDER 00123	1234567	11223345	ARR		1234 568		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
CDMS-02	20-APR-2008	Pending	WONDER 00123	1234567	11223345	ARR		1234 568		Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
CDMS Records Not Matched to Argus Case (2)																	
CDMS-01	20-APR-2008	Pending	WONDER 00123	1234567	11223345	AKA		1234 569		Unconsciousness	10043071	04-NOV-2005	04-NOV-2005		Yes	Recovered	Probably
CDMS-02	20-APR-2008	Pending	WONDER 00123	1234567	11223345	MWB		1234 569		Kidney Failure	10043071	04-NOV-2005			No	Outgoing	Probably

Legend: Pending (red), Accepted (yellow), Resolved (green)

Buttons: Print List, Close

Argus Safety's focus on business process efficiency allows

pharmacovigilance departments to focus on a drug's clinical effectiveness at lower overall cost. It provides complete insight into a drug's safety profile necessary to let executives make timely, science-based decisions on their products and portfolios.

### Single Global Database Including Japanese Safety Operations

Drug safety operations in Japan can be a significant portion of a company's global drug safety operations, which requires processes, regulatory reports and interfaces to be tailored to the Japanese needs. Argus Safety is a true single global safety database that supports operations in all regions including Japan. Argus Safety Japan is tailored for end-to-end Japanese safety processes, provides a localized interface and translation support, and is fully compliant with MHLW / PMDA guidance and reporting requirements including support of the Japanese E2B message and its companion J file.

### Securely Manages Multiple Enterprises

Argus Safety's multi-tenancy capabilities enable health sciences organizations and contract research organizations (CROs) to securely maintain separate partitions of data within a single database, significantly reducing the hardware and resources required for ongoing maintenance, yet enabling users to securely manage work across the partitions.

Enterprise ID	Link	Priority	Receipt Date	Date Open	Case Number	Product Name	Event P1	Case Type	Reporter Type	Assigned To
001-000001		High	20-Mar-2010	20-Mar-2010	000001	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned
001-000002		High	20-Mar-2010	20-Mar-2010	000002	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned
001-000003		High	24-Feb-2010	24-Feb-2010	000003	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned
001-000004		High	07-Apr-2010	07-Apr-2010	000004	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned
001-000005		High	07-Apr-2010	07-Apr-2010	000005	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned
001-000006		High	20-Apr-2010	20-Apr-2010	000006	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned
001-000007		High	20-Apr-2010	20-Apr-2010	000007	Discontinuation of Comparison	Adverse/Death	Discontinuation of Comparison	Physician (US/CA)	Unassigned

### Integrating Safety and Risk Management

Pharmacovigilance departments are struggling with increasing case volumes, disparate data sources and complex business partnerships, challenging their ability to analyze and understand the safety data. The industry is struggling to maintain process efficiencies while managing product risk profiles in real time.

Oracle Argus Safety is part of Oracle's set of comprehensive solutions to manage pharmacovigilance, signal detection and proactive risk management across the product lifecycle. Argus Safety seamlessly integrates with Oracle Argus Insight, Empirica Topics and Empirica Signal to provide a comprehensive safety and risk management platform.

Argus Safety has native risk management capabilities to address regulatory requirements and manage a product's benefit:risk profile, including reporting automation using advanced conditions, documentation storage, collection of information for advanced visualization and for tracking pregnancy registries. In addition, it can be seamlessly integrated with signal

**ORACLE'S ARGUS SAFETY 7.0 TECHNICAL SPECIFICATIONS**

- Client:
  - Windows XP SP 3 (IE 7 or 8), and Windows 7 (IE8)
- Middle Tier:
  - Windows 2008 Server
- Database:
  - Oracle 11gR2
  - Windows 2008 SP2 Server

detection and management systems to proactively mine safety data. Companies can leverage the Argus Safety suite to ensure a proactive approach to managing product safety, from clinical development to post-marketing.

**Industry Proven and Accepted**

Argus Safety has been in use for over a decade at some of the industry's leading companies, including global pharmaceutical, biotech, CRO and medical device manufacturers. It is continuously enhanced through a defined and planned product roadmap.

**Reduce project risk and cost with Oracle Consulting Services**

Consultants from Oracle Health Sciences are part of a global consulting organization with extensive domain expertise and in-depth experience implementing Oracle's health care and life sciences solutions. Oracle's consultants complement Oracle Health Sciences products to provide a comprehensive solution. They can help organizations:

- *Reduce project risk and improve quality* with Oracle's distinctive resources and expertise
- *Lower total cost of ownership* with Oracle's complete solution
- *Realize faster time to business value* by leveraging Oracle's unique library of consulting assets and accelerators

Oracle Health Sciences' consultant team is 100% dedicated to Oracle Health Sciences products and have many years of experience implementing these healthcare and life sciences solutions. It is composed of a global team of product experts who leverage their close ties to Oracle's product strategy and development teams, utilize standard Oracle methodologies (OUM aware and certified), participate in numerous international standards-setting bodies (such as HL7 steering committee, CDISC), and embrace a partner-friendly strategy. All while backed up by the power of Oracle Corporation's global consulting organization. Oracle Health Sciences consultants are uniquely positioned to ensure project success.

**Contact Us**

For more information about Oracle's Argus Safety, please visit the [Oracle Health Sciences Applications website](#) or call your [local Oracle office](#) or +1.650.506.7000 to speak to an Oracle representative.

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# 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.

# 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
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- 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.

# MANAGING CLINICAL-TO-SAFETY RECONCILIATION WITH ORACLE'S ARGUS RECONCILIATION



ORACLE'S ARGUS RECONCILIATION IS PART OF THE ARGUS SAFETY SUITE. IT SUPPORTS THE CLINICAL TO SAFETY RECONCILIATION PROCESS TO:

- Deliver Significant Operational Efficiency Gains
- Lower The Cost Of Clinical-To-Safety Reconciliation
- Help Integrate Safety And Risk Management Activities

Companies are increasingly shifting their focus to a more holistic view of product safety from clinical development continuing through post-market surveillance. The Oracle Argus Safety Suite is an integrated platform designed specifically to address the life sciences industry's complex pharmacovigilance requirements. Oracle's Argus Reconciliation, a component of the Argus Safety Suite, helps life sciences companies simplify the cumbersome clinical-to-safety reconciliation process.

### Improved Operational Efficiency

Inconsistent data between disparate clinical and safety systems can lead to false conclusions about the safety profile of a drug. Reconciling this pharmacovigilance information across departments is a significant challenge. Life sciences organizations spend significant time and resources to overcome this data silo challenge by performing manual quality checks.

Argus Reconciliation reduces the burden of this process by reconciling drug safety data from clinical data management systems with the Oracle Argus Safety database. It significantly improves productivity by eliminating double data entry and reducing the possibility of introducing errors. It's intuitive and user-friendly graphical interface helps identify discrepancies quickly and easily, helping companies shorten the reconciliation process.

**INTERACTIVE RECONCILIATION REPORT**

Total Number of Rows (48)  Show Discrepancies Only  Displaying Rows 101-200  100

Unmatched Records	Date Ident/Res	Status	Study #	Inv ID	Pat ID	Init.	Death Date	SAE ID	Verbatim Suffix	LLT	Start	Stop	Intensity	Treatment	Outcome	Causality	
<input type="checkbox"/> Yes					11223344												
200009 000001		Resolved	WONDER 00123	1234567	11223344	AKA	N/A										
Argus-01			WONDER 00123	1234567	11223344	AKA		1234 567	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
CDMS-01	20-APR-2006 20-APR-2006	Resolved	WONDER 00123	1234567	11223344	AKA		1234 567	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
Argus-02			Accepted All Pending Record Level Reconciliation Options		44	AKA		1234 567	2	Fever	10016588	04-NOV-2005	04-NOV-2005	Mild	No	Recovered	Probably
CDMS-02	20-APR-2006 20-APR-2006	Resolved	Set All Accepted to Pending		44	AKA		1234 567	2	Fever	10016588	04-NOV-2005	04-NOV-2005	Mild	No	Recovered	Probably
200009 000002		Pending	WONDER 00123	1234567	11223344	AKA	N/A										
Argus-01			WONDER 00123	1234567	11223345	JHW		1234 568	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild		Recovered	Probably
CDMS-01	20-APR-2006	Pending	WONDER 00123	1234567	11223345	JHW		1234 568	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mod		Reconciliation Options Accepted Pending	Probably
200009 000003		Pending	WONDER 00123	1234567	11223344	AKA	N/A										
Argus-01			WONDER 00123	1234567	11223345	AHR		1234 568	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Moderate	Yes	Recovered	Probably
CDMS-01	20-APR-2006 20-APR-2006	Accepted	WONDER 00123	1234567	11223345	AHR		1234 568	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Severe	Yes	Recovered	Probably
Argus-02			WONDER 00123	1234567	11223345	AHR		1234 568	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
CDMS-02	20-APR-2006	Pending	WONDER 00123	1234567	11223345	AHR		1234 568	1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Yes	Recovered	Probably
<b>CDMS Records Not Matched to Argus Case (2)</b>																	
CDMS-01	20-APR-2006	Pending	WONDER 00123	1234567	11223345	AKA		1234 568	3	Unconsciousness	10043071	04-NOV-2005	04-NOV-2005		Yes	Recovered	Probably
CDMS-02	20-APR-2006	Pending	WONDER 00123	1234567	11223345	MWB		1234 568	1	Kidney Failure	10043071	04-NOV-2005		Mild	No	Outgoing	Probably

Pending  Accepted  Resolved

Interactive Reconciliation Report

After Argus Reconciliation automatically extracts data from clinical data management systems and reconciles it with the Argus Safety database, it generates an advanced, interactive reconciliation report. This report allows for easy visual determination of case-by-case data discrepancies. Argus Reconciliation can also be used to generate full reconciliation reports. For maximum flexibility, comparison and update routines are implemented as database-stored procedures.



**ORACLE'S ARGUS  
SAFETY TECHNICAL  
SPECIFICATIONS**

- Client:
  - Windows XP SP1,2 or 3 (IE 7 or 8), and Vista SP1 (IE7 or 8) client)
- Middle Tier:
  - Windows 2003 Server
- Database:
  - Oracle 11g
  - HP-UX Itanium 11.31
  - Sun Solaris (SPARC) 9, 10
  - Windows 2003 Server

**Lower cost of reconciliation and pharmacovigilance**

The disparate nature of safety and clinical systems forces companies to divert limited resources to redundant tasks such as double-data entry and quality checks instead of focusing on strategic pharmacovigilance activities. This can significantly affect the cost of pharmacovigilance operations.

Argus Reconciliation eliminates the need for data entry and vastly simplifies the process of reconciliation. Because it significantly reduces the number of hours that full-time employees spend on data reconciliation, Argus Reconciliation delivers an immediate return on investment (ROI) to life sciences companies. In addition, pharmacovigilance managers are thus able to focus their resources on valuable drug safety analysis rather than resource-intensive reconciliation.

**Integrated Safety and Risk Management**

Argus Reconciliation is part of the Argus Safety Suite, an integrated platform that supports end-to-end safety and risk management activities. The Argus Safety Suite offers native risk management capabilities to address regulatory requirements and manage a product's benefit:risk profile (including reporting automation using advanced conditions, documentation storage, collection of information for advanced visualization and for tracking pregnancy registries.) It can also be seamlessly integrated with signal detection and risk management systems for proactive data mining.

Companies can leverage the Argus Safety Suite, including Argus Reconciliation, to increase linkages across clinical safety and post-marketing surveillance, enabling companies to focus on managing a product's safety profile.

# ORACLE ARGUS DOSSIER

## KEY FEATURES

### REPORTING FEATURES

- Global, standardized, and repeatable templates for product-level reports
- XML-based scripting language for writing templates
- A worldwide marketing authorization table template
- Full reporting schedule calendar with complete delineation of DLP for initial and follow-up reports
- One-time configuration to automatically schedule periodic reports throughout a product's lifecycle
- Generation and inclusion of MedWatch, CIOMS II, VAERS expedited reports, line listings, and summary and other tabulations

### MANAGEMENT FEATURES

- Collaboration platform for report authoring and submission
- Management reports for resource estimation, planning, and status tracking
- Audit records for all document management activities
- Distribution of reporting tasks to individual team members based on report sections
- Workflow tools for controlling and managing report authoring and submission cycles
- Customizable e-mail notification features
- Ability to edit generated templates with Microsoft Word
- Generation of submission-ready dossiers in PDF format with bookmarks
- Complete interface with Documentum for intermediate draft and final reports

*Oracle Argus Dossier is a collaborative, Web-based solution that manages the entire lifecycle of periodic dossiers, from planning, collaborating, producing, and submitting to task tracking and management. Designed in collaboration with leading pharmaceutical companies, it significantly streamlines and simplifies the document writing process for periodic report production. It manages and plans the reporting schedule ahead of submission deadlines. Oracle Argus Dossier puts data into perspective and creates a holistic picture of a drug with respect to its exposure over a period of time. In conjunction with Oracle Argus Safety—a comprehensive foundation for case management and reporting—Oracle Argus Dossier is a critical component of pharmaceutical companies' pharmacovigilance and risk management strategies.*

### The Periodic Dossier and Report Challenge

To ensure the safety and marketability of pharmaceutical products, periodic dossiers and reports must be filed with regulatory agencies. Pharmaceutical companies review the cumulative safety information obtained from a wide range of sources—including spontaneous reports and clinical study results—on a periodic basis and submit the findings to regulators worldwide. The exact type of report submitted varies by country and with the approval status of the medicine. Preapproval reports may provide cumulative information or contain aggregate information specific to the reporting period. Postapproval cumulative reports of safety update and evaluate the worldwide safety experience with a medicine at defined time points after approval. Generally speaking, these reports provide succinct summary information, together with an evaluation of the risk/benefit profile of approved medicines in light of new or changing information. This evaluation is designed to help ascertain whether further investigations need to be carried out and whether changes should be made to the approval and/or to the medicine's labeling. Creating such reports is a data- and regulation-intensive task.

### Product Overview

Oracle Argus Dossier simplifies creation of periodic reports. It not only provides global and product-level templates but is also able to generate new periodic reports based on those templates and provides you with a flexible XML-based scripting language for writing new templates. Because it maintains a full reporting calendar, you know when to file the reports relative to the data lock point (DLP) date. Besides offering features that facilitate report creation, Oracle Argus Dossier helps manage

## RELATED PRODUCTS

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- Oracle Argus Interchange
- Oracle Argus Reconciliation
- Oracle Argus Unblinding

the entire process by providing a platform for tracking report authoring and submission, generating management reports, and providing audit records.

### **More Rapidly Produce Periodic Dossiers**

Oracle Argus Dossier's role-based workflow eliminates resource-intensive, manual work and saves substantial hours of employee work. It structures the publishing process so regulatory obligations can be met in a timely manner. Drug safety departments can utilize Oracle Argus Dossier's advanced calendar management capability to manage the entire reporting lifecycle, from planning, collaborating, producing, and submission to task tracking and management.

### **Focus on Important Information**

Oracle Argus Dossier provides visibility into data, ensuring that drug safety departments are able to collect the right information. It enables companies to maximize the time they spend on safety analysis rather than time-consuming, remedial tasks. Data is presented in the correct context—providing a holistic picture of pharmaceutical products with respect to their exposure over a period of time.

### **Fully Integrated Safety System**

Oracle Argus Dossier seamlessly integrates with other products in the Oracle Argus product family, so pharmaceutical companies have the option of adding further functionalities. When integrated with Oracle Argus Safety, Oracle Argus Dossier becomes a key part of a comprehensive risk management system.

# ORACLE ARGUS INSIGHT

## KEY FEATURES AND BENEFITS

### FEATURES

- Multidimensional reports
- Analysis of safety data
- Denormalized data for efficient querying
- More than 150 standard reports
- Ad hoc querying and reporting with report writer
- Drill-down analysis through text or graphs with cubes
- Dashboard indicators to provide timely, complete information to all user levels
- Automated scheduling and e-mailing
- Derivation rules for creating computed values in the data mart

### BENEFITS

- Provides visibility into strategic data across the enterprise
- Provides users and managers with the ability to quickly and easily access required information
- Eliminates the need to involve IT in running reports and queries
- Uncovers key, statistically significant data for managing the risk/benefit profiles of drugs
- Supports key decision-making by compiling and analyzing data

*Oracle Argus Insight is an analysis tool for safety data adopted by global pharmacovigilance specialists. It provides comprehensive analysis of pharmaceutical safety data for making key business decisions quickly and confidently. With a comprehensive knowledgebase, an extensive report library, simplified querying and reporting, and easy data access, Oracle Argus Insight is a comprehensive data analysis solution that delivers analytics and insight into safety data.*

### The Data Analysis Challenge

Bringing new drugs and medical devices to market has always been a complicated process involving corporations, government, laboratories, doctors, and patients. However, in recent years, the number and complexity of clinical trials required to prove the efficacy of therapies are increasing. In addition, more parties—sponsors, contract (or clinical) research organizations (CROs), trial sites, regulatory agencies, and medical institutions—are managing research and generating data. Finally, new and observational safety datasources are emerging, including insurance claims, diagnostic tests, and prescriptions. Increasing amounts of data from multiple sources have made the collection and analysis of safety data more complex. Health science companies require a tool that can turn data into insight so managers and executives can make better decisions based on timely, relevant information.

### Product Overview

Oracle Argus Insight offers multidimensional analysis of pharmaceutical safety data to create reports that enable employees to make key business decisions quickly and confidently. Whether conducting analyses on workflow or product data, managers realize improved performance. The ability to rapidly create ad hoc queries without restrictive parameters allows user-defined analysis and visualization of safety data. In addition, Oracle Argus Insight's querying features eliminate the need for IT to run queries in SQL, so business users are empowered to get the information they need. Data can be accessed securely over the Web for instant, global decision-making.

### Comprehensive Knowledgebase

Oracle Argus Insight's flexible extract, transfer, and load (ETL) engine populates a data warehouse with drug safety data and information such as sales, clinical trials, or product dictionary data to create a comprehensive knowledgebase. With denormalization, Oracle Argus Insight can extract key information from a company's data mart to deliver efficient querying, drill-down analysis, and report generation—all without impeding the daily use of mission-critical drug safety databases.

## 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

## Extensive Report Library

Argus Insight delivers more than 150 standard reports that provide knowledge on regulatory compliance, products and licenses, pharmacovigilance, productivity, case volume, and case processing. The reports can highlight medical analysis and track key performance indicators (KPIs). They can be readily shared in Microsoft Excel for further drill-down or in Adobe Acrobat for external distribution. Finally, users can define report outputs to meet their own regulatory reporting and/or corporate reporting requirements. As a result, the standard reports can be configured to meet the needs of individual companies.

## Querying and Reporting for Business Users

With Oracle Argus Insight, medical reviewers can create queries and custom reports from millions of cases in just minutes. Companies can clearly analyze and visualize safety data and event-level information to support risk management and signal detection. Users of all skill levels can conduct simple or advanced queries, eliminating the need for IT to run complex SQL queries. Built-in query methods include

- **Query by example.** Simple queries can be constructed from an easy-to-use interface that gives business users easy access to relevant data.
- **Filters.** Filters enable several parameters to be incorporated into a single, complex query while maintaining usability.
- **Advanced conditions.** The most advanced query tool allows granular queries by enabling users to set conditions on every aspect of the safety process.

## Easy Access to Data

Argus Insight enables medical reviewers to drill down through all data levels, using common attributes to obtain the focus they desire. Numerous preformed, standard reports for pharmacovigilance minimize startup time. First-time users can quickly access data and then efficiently produce and analyze reports that provide immediate business impact by improving decision-making. In addition, easy access to data supports risk management processes and speeds response to regulatory inquiries.

## Fully Integrated Safety System

Oracle Argus Insight seamlessly integrates with the Oracle Argus product family. Oracle Argus Safety and Oracle Argus Perceptive can both be integrated with Oracle Argus Insight to deliver a comprehensive risk management tool.

# ORACLE'S ARGUS PERCEPTIVE HELPS LIFE SCIENCE COMPANIES OPTIMIZE THEIR PORTFOLIO BENEFIT:RISK PROFILE



THE ORACLE RISK MANAGEMENT SUITE IS AN ADVANCED SOLUTION THAT ENABLES PRODUCT STEWARDSHIP AND HELPS DRIVE AN ORGANIZATION'S COMPREHENSIVE RISK MANAGEMENT IMPERATIVE, INCLUDING:

- RISK IDENTIFICATION
- RISK ANALYSIS
- RISK MITIGATION
- PORTFOLIO MANAGEMENT

In the CIOMS VIII era, life science companies must holistically address all aspects of risk management and product stewardship, from clinical development through post-marketing. A 360° view includes risk identification, risk analysis, risk mitigation and portfolio management. The Oracle Argus Risk Management Suite helps companies focus on a product's benefit:risk profile while also optimizing the overall portfolio. Oracle's Argus Perceptive is a key component of this solution suite.

### Risk Identification

Argus Perceptive helps companies proactively detect safety signals via real-time monitoring of product-event combinations as well as leveraging industry-standard and advanced algorithms for data mining. A complimentary system of primary and secondary alerting, based on therapeutic area and/or safety assessment criteria, supports risk assessors by automating signal detection and identification.

Argus Perceptive gathers data from multiple sources for more accurate signal detection capability. External data and clinical information may also be leveraged to identify additional signals, or to provide a logical context for validation of existing alerts. Recent data can also be used to retrospectively data mine for past correlations.

Traditional qualitative methodologies such as designated medical events (DME) are implemented through the use of primary alert configurations while algorithms are supported via quantitative, secondary alerting. Argus Perceptive offers standard but also innovative algorithms to provide risk assessors with a full spectrum of best practices for identifying potential signals:

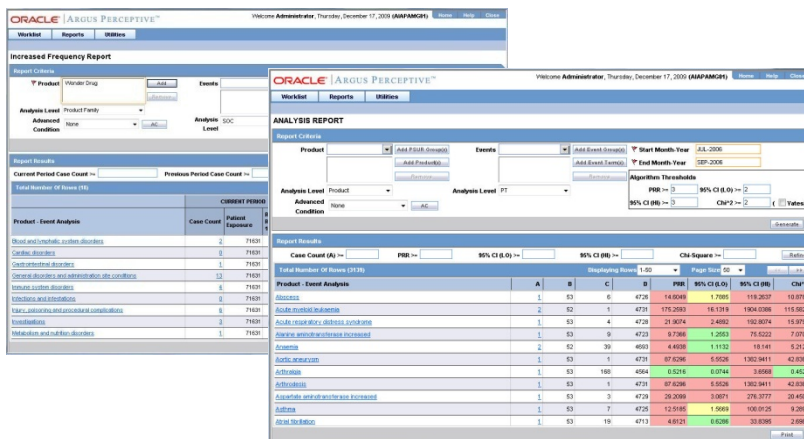
Industry-standard and advanced algorithms unique to Argus Perceptive
Proportional Reporting Ratios (PRR)
Chi-Square ( $\chi^2$ )
95% Confidence Intervals (95% C.I.)
Complete SMQ support
Intra-Product PRR
Case Scoring
Increased Frequency Reporting based on Patient Exposure

Signal detection, however, is only the first step in assessing a product's risk. Crucial to regulations such as CIOMS VIII, Argus Perceptive provides the framework for a more comprehensive structured signal management process to analyze and mitigate risk, making it a unique and complete solution for managing benefit:risk profiles in the corporate portfolio.

**Risk Analysis**

Beyond signal detection, Argus Perceptive also provides an integrated platform for risk analysis, enabling real-time analysis as soon as a risk is detected, as well as providing the ability to stratify cases to further understand the public health impact. To ensure regulatory compliance, an integrated environment also supports the tracking of regulatory inquiries for on-going risk management obligations from RMPs and REMS. Advanced features include:

Advanced risk analysis features	
<b>Summary Report</b>	a breakdown of the case series, automatically calculated and included with each triggered alert
<b>Analysis Report</b>	multifaceted report with color-assisted visualization of multiple algorithmic thresholds
<b>Content Matrix</b>	intuitively aids the signal analyst in finding neighboring cases to add to the case series
<b>Increased Frequency Report</b>	Color-differentiated report that is supported by patient exposure data as defined by the FDA increased frequency algorithm



For additional analysis, Argus Perceptive seamlessly integrates with Oracle’s Argus Insight, the business intelligence and analytics tool for pharmacovigilance. Argus Insight provides the risk assessor with powerful querying capabilities, a predefined library of multidimensional reports, user-friendly ad hoc report creation, and audited case series updating and freezing functionality. With a single click, case series can be passed from Argus Perceptive to Argus Insight and vice versa, providing the ultimate analytic flexibility.

**Risk Mitigation**

Confirmed risks must be addressed within company SOPs to support REMS and RMP requirements. Argus Perceptive offers a structured approach for risk mitigation, ensuring adherence to the company pre-defined SOP for triage, assessment, mitigation and follow-up. This includes features such as flexible and fully configurable workflows, including group worklists, workflow rules, due dates and action items. Actions resulting from a confirmed signal are tracked and documented in a collaborative environment, while risk assessors may also schedule reports and queries to

**ORACLE'S ARGUS PERCEPTIVE TECHNICAL SPECIFICATIONS**

- Web server: Windows 2003 SP2 Standard & Enterprise
- Database server: Windows 2003 SP2 Standard & Enterprise, Red Hat Linux 5.0
- Oracle server: Oracle Standard & Enterprise 10.2.0.4, 11.1.0.7
- Client: XP Pro SP3 / Vista SP1 all versions

ensure timely assessments. Argus Perceptive thereby enables a continuous process of assessment and mitigation based on a product's identified risk.

Argus Perceptive can store the company's global Signal Workup Document template so that the latest version is instantly and centrally available to signal analysts. Check-out and check-in as well as version history is supported by the application. The final Signal Workup Document is stored together with the triggered alert so that all relevant information is in one place.

Through the process of archiving both confirmed signals and alerts evaluated as non-risks for the time being, risk assessors build an invaluable knowledgebase in Argus Perceptive over time. The application can be configured to continue monitoring for new cases that can awaken latent, archived alerts in the knowledgebase and give analysts the opportunity to reevaluate the situation. Additionally a watchlist with reminder functionality keeps important alerts on the radar screen.

Management gains visibility into risk metrics for each product via executive dashboards, providing the ability to make safety-based portfolio decisions. Importantly, Argus Perceptive also enables companies to rapidly respond to regulatory inquiries, helping to ease the burden of compliance.

Argus Perceptive, in conjunction with Argus Insight and Oracle's Argus Dossier, allows companies to manage the benefit:risk profile across their entire product portfolio. Oracle's risk management solutions thus help life science companies move beyond mere regulatory compliance to focus on holistic product stewardship.