

DRIVING PRODUCT STEWARDSHIP AND REGULATORY COMPLIANCE WITH ORACLE'S ARGUS SAFETY



ORACLE'S ARGUS SAFETY IS A COMPREHENSIVE PHARMACOVIGILANCE PLATFORM DESIGNED TO ENABLE LIFE SCIENCES COMPANIES TO EXCEL IN PRODUCT STEWARDSHIP. WITH ARGUS SAFETY, COMPANIES CAN:

- ENSURE REGULATORY COMPLIANCE
- FOCUS ON PHARMACOVIGILANCE
- INTEGRATE SAFETY AND RISK MANAGEMENT

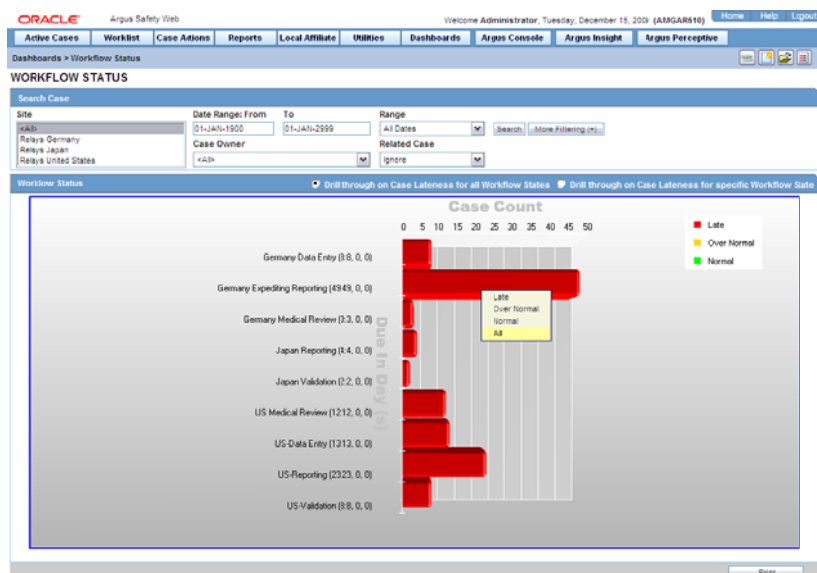
Oracle's Argus Safety is the cornerstone of the Argus Safety suite, a comprehensive platform designed specifically to address the life sciences industry's complex pharmacovigilance requirements. Argus Safety incorporates advanced functionalities to help companies ensure regulatory compliance, improve clinical trial visibility and integrate safety and risk management initiatives into a comprehensive view of product stewardship.

Ensuring Regulatory Compliance

Life sciences organizations must ensure that they are compliant with global regulations and guidance, including those of EMEA, 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 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 a comprehensive set of 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 companies 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.



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Product Stewardship from Clinical Development to Post-Marketing

Companies are increasingly shifting their focus to a more holistic view of product stewardship beginning in clinical development and continuing through post-market surveillance. Argus Safety supports this by facilitating a company's end-to-end pharmacovigilance programs. By integrating SAEs from clinical trials, companies have the opportunity to manage efficacy earlier in the drug lifecycle and potentially address public health concerns sooner.

Argus Safety has been developed with input from leading life sciences companies and industry thought leaders. Advanced functionality such as dynamic workflows, worklist management, company-defined reporting rules and extensive automation are incorporated to ensure maximum case processing efficiency, enabling pharmacovigilance departments to focus on a drug's clinical effectiveness at lower overall cost.

Additional modules, such as Oracle's Argus Dossier and Oracle's Argus Reconciliation, can also be fully integrated with Argus Safety, providing the ability to readily reconcile SAEs from clinical trials as well as efficiently manage periodic reports.

Integrated Safety and Risk Management Platform

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

The Argus Safety suite is a unified platform designed to address the industry's end-to-end safety and risk management needs. It includes a comprehensive tool set for expedited and periodic reporting, signal detection and management, clinical trial SAE reconciliation and partner AE management. Companies can leverage the Argus Safety suite to ensure a holistic view of their product safety profile from development to post-marketing.

CONSULTING SERVICES

Oracle offers a complete suite of consulting and training services that help customers implement and become productive with Argus Safety as quickly as possible.

ORACLE'S ARGUS SAFETY 5.1 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

INTERACTIVE RECONCILIATION REPORT

Total Number of Rows (40) Show Discrepancies Only Clear Filter Displaying Rows 101-200 Page Size 100

Unmatched Records	Date	Status	Study #	Inv ID	Pat ID	Int.	Death Date	SAE ID	SAE ID Suffix	Verbatim	LLT	Start	Stop	Intensity	Treat ment	Outcome	Causality	
<input type="checkbox"/> Yes					11223344													
300019 300019		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			WONDER 00123	1234567	11223344	AKA		1234 567		2	Fever	10016556	04-NOV-2005	04-NOV-2005	Mild	No	Recovered	Probably
CDMS-02	20-APR-2006 20-APR-2006	Resolved	WONDER 00123	1234567	11223344	AKA		1234 567		2	Fever	10016556	04-NOV-2005	04-NOV-2005	Mild	No	Recovered	Probably
300019 300019		Pending	WONDER 00123	1234567	11223344	AKA	N/A											
Argus-01			WONDER 00123	1234567	11223340	JKW		1234 568		1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Reversed	Probably	
CDMS-01	20-APR-2006	Pending	WONDER 00123	1234567	11223345	JKW		1234 568		1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	Reconciliation Op504d	Accepted	Probably
300019 300019		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	Mild-to-sev	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	11223346	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	11223346	AHR		1234 568		1	Tachycardia	10043071	04-NOV-2005	04-NOV-2005	Mild	No	Outgoing	Probably
CDMS Records Not Matched to Argus Case (2)																		
CDMS-01	20-APR-2006	Pending	WONDER 00123	1234567	11223345	AKA		1234 569		3	Unconstruc tured	10043071	04-NOV-2005	04-NOV-2005		Yes	Recovered	Probably
CDMS-02	20-APR-2006	Pending	WONDER 00123	1234567	11223345	MWB		1234 569		1	Kidney Failure	10043071	04-NOV-2005		Mild	No	Outgoing	Probably

Pending
 Accepted
 Resolved

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.

Contact Us

For more information about Oracle's Argus Safety suite, please visit the [Oracle Health Sciences applications website](#) or call +1.800.ORACLE1 to speak with an Oracle representative.

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