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

# ORACLE

HEALTH SCIENCES

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.

Active Cases Worklist Case Actions Repor		ons Reports	Local Affiliate	ies Dashboa		pards	ds Argus Co		vsole	Argus Insight	Argus Percepti	we		
shboards > Work	flow Status													📼 🎴 🚅
ORKFLOW ST	TATUS													
earch Case														
te			ate Range: Fron			Range								
Ab			01-JAN-1900	01-JAN-2999		AI Date			٣	Search	More	Filtering (+)		
Relaya Germany Relaya Japan			Case Owner			Related	Case							
Relays United States	8		(A)Þ		<b>M</b>	Ignore			-					
lorklow Status				🗢 Drill	through	on Case	Laten	ess fo	r all W	lorkflow	States	Drill through or	n Case Lateness fo	r specific Workflow S
							_	Ca	150	Cou	int			
						0	5 1	0 15	20	25 30	35 40	45 50		Late
														Over Normal
				Germany Data Entry (	8.8.0.0)									Normal
										_				
			Gemany Ex	editing Reporting (49	49, 0, 0)									
										Late Over No				
			Gem	any Medical Review (	3.3, 0, 0)					Normal	ima			
						ē i	1			All				
				Japan Reporting (	\$4.0.0	9								
						2 <b>1</b>								
				Japan Validation (	22.0.0									
						9								
			U:	Medical Review (12	12.0.0	2								
						8								
				US-Data Entry (13	13.0.0									
					,,,									
				US-Reporting (23	23.0.01									
				US-Validation [	8.0.01									



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

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

## 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.

ORACLE			Welco	me Administrat	tor, Tuesday, December 15, 2009 (AMG	AR510) Home Help	Close
Code Lists	Business Configuration	Access Management	System Configuration	Tools			
EXPEDITED REI Browser Organized By C	PORT RULES	[RA] US (FDA) 15 day (MK Report Name			TReport Destination		
Contains M Displaying Rows 1		[HA] US (FDA) 15 day (IIKT)       Active       Poreign of events to inc       Domestic       Poreign	Distribute Reports Blind S	tudy Products	Protect Reporter and Pa Report on Study Drug n Active Molety		Case
B- MEXICO ( B- METHERL B- NORWA) B- POLAND B- PORTUG B- SPAIN (S B- SWEDEN B- SWEDEN B- SWEDEN	ANDS (8) (5) (4) AL (4) (5)	Force Distribute Form US FDA MedWatch 3500- Local Comment Type Language English	days before due A Drug Clinical Reference Isprore	Type	Listedness (Event) Unisted Seriousness FatalLife Threatening Seriou Gone Severity (Event) gone	us (Event) Serious (Case	2) 2) 2)
IB- 🛅 UNITED K	NGDOM (10)	Product Specific Product Group			Family Name		~
- Calinves (#- Calinves)	Spational Drug (4) Spational Vaccine (0) Med Device (2) Jeted Drug (2)	As Reported (Event)	Include Non-Clinical Trial Cases As Determined (E			As Determined (Case)	
-8.0	HA] US (FDA) 15 day (MKT / Dom) HA] US (FDA) 15 day (MKT / Frgn) sted Vaccine (2)	Advanced Condition (None) Comments	M ignore	× 	Responsible Group	ignore Cover Letter	*
				5avi	e Copy Rule Add Rule	Delete Print	

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 Nu	mber of Rov	/s (48)	<b>*</b> 5								Clea	n Filtens D		101-200	M Pa		100 🛩	<c></c>	2.
Inmichd lecords	Date Ident/Res	Status		Study #	Inv ID	Pat ID	Init.	Death Date	SAE-	SAE ID Suffix		шт	Start	Stop	Intensity	Treat-	Outcome	Causality	
Yes			¥			11223344													
2000005		Repoived		WONDER 00123	1234607	112233-44	AK	N/A											1
1949-01				WONDER 00123	1234567	11223344	AKA		1234 607	1	Tashysardia	100-1307	04-NOV-2005	04 NOV 2005	Mid	Yes	Recovered	Probably	
DMS-01	20-APR-2008 20-APR-2008	Resolved		WONDER	conciliation		AKA		1234	1	Tashysardia	100-1307	04-NOV-2005	04 NOV 2005	Mild	Yes	Recovered	Probably	
rgus-02				epted All Pe			AKA		1234 667	2	Fever	10016580	04-NOV-2005	04 NOV 2005	Mild	No	Recovered	Probably	1
DMS-02	20 APR 2008 20 APR 2008	Resolved	Set	All Accepte	d to Pending	44	АКА		1234 667	2	Fever	10016560	04-NOV-2005	04N0V2005	Mild	No	Recovered	Probably	
000005		Pending		WONDER 00123	1234507	112233-44	AK	N/A											ĺ
rpus 01				WONDER 00123	1234567	11223345	JIOW		1234 568	1	Tachycardia	10043071	04 NOV 2005	04 NOV 2005			Recovered	Probably	I
	20-APR-2008	10000	•	WONDER 00123	1234667	11223345	J10W		1234 668	1	Taehyeardia	10043071	04 NOV 2005	04 NOV 2005	Mad	cepted	non Upsons	Probably	
00003		Pending		WONDER 00123	1234667	112233-64	AK	N/A							Pe	nding			
agus-01				WONDER 00123	1234567	11223345	AHR		1234 568	1	Tachycardia	10043071	04-NOV-2005	04 NOV 2005	Moderat	e Yes	Recovered	Probably	
DMS-01	20-APR-2006 20-APR-2006	Accepted	•	WONDER 00123	1234567	11223345	AHR		1234 668	- 1	Tachycardia	10043071	04-NOV-2005	04NOV2005	Severe	Yes	Recovered	Probably	
rgus-02				WONDER 00123	1234567	11223348	AHR		1234 668	1	Tachycardia	1004307	04 NOV 2005	04 NDV 2008	Mild	Yes	Recovered	Probably	l
DMS-02	20-APR-2006	Pending																	k
CDMS R	ecords Not	Matched	to A	irgus Case	(2)														ľ
DMS-01	20-APR-2008	Pending		WONDER 00123	1234567	11223345	AKA		1234 560	3	Unconscious	10043071	04-NOV-2005	04NDV2005		Yes	Recovered	Probably	ł
DMS-02	20-APR-2008	Pending		WONDER 00123	1234507	11223345	MWD		1234 508	1	Kidney Failure	1004307	04-NOV-2005		Mild	No	Outpoing	Probably	
Per	ding		A	ccepted		Resolve	đ									0	Print List	Close	ľ

# **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 <u>Oracle Health Sciences applications website</u> or call +1.800.ORACLE1 to speak with an Oracle representative.

Copyright © 2009, Oracle and/or its affiliates. All rights reserved.

This document is provided for information purposes only, and the contents hereof are subject to change without notice. This document is not warranted to be error-free, nor is it subject to any other warranties or conditions, whether expressed orally or implied in law, including implied warranties and conditions of merchantability or fitness for a particular purpose. We specifically disclaim any liability with respect to this document, and no contractual obligations are formed either directly or indirectly by this document. This document may not be reproduced or transmitted in any form or by any means, electronic or mechanical, for any purpose, without our prior written permission.

Oracle is a registered trademark of Oracle Corporation and/or its affiliates. Other names may be trademarks of their respective owners. 0408

