

# ORACLE ADVERSE EVENT REPORTING SYSTEM

## **ORACLE** HEALTH SCIENCES

- Single repository of global adverse event and complaint data
- Powerful case management functionality
- Easy-to-use interface
- Multi-lingual/Japanese support
- Local affiliate support
- Query all adverse event data from one simple interface
- Automated submission wizard for determining reporting requirements
- Automated report generation and distribution
- Full complement of regulatory reports, including MedWatch 3500a Drug, MedWatch 3500a Device, CIOMS I, NDA Periodic, IND Safety Update, PSUR, Annual Safety Report, VAERS, BfArM, Yellow Card, and many more
- One-step document attachment
- Robust privacy features
- Secure unblinding functionality
- Graphical case overview provides interactive presentation of key case information
- Audit trail and product tracking enables monitoring of safety issues and incidents over time
- Capture and display data in users' local language
- Robust product repository, including product label maintenance facility

*Oracle Adverse Event Reporting System (AERS) is a comprehensive solution for product safety monitoring and compliance, and an integral part of the Oracle life sciences application suite. With its unparalleled integration with Oracle Clinical and Oracle Thesaurus Management System, Oracle AERS provides companies with a solution to help manage adverse events and reduce risk.*

### **Industry Challenges**

Biopharmaceutical, vaccine, medical device companies, and contract research organizations (CROs) are constantly challenged with meeting time-critical regulatory requirements using limited resources. They must identify and manage safety events before they become issues, and they need to maintain strict compliance with evolving regulations. To manage critical business processes, they require clear visibility into their data.

### **The Solution: Oracle Adverse Event Reporting System**

Oracle AERS provides a single global solution with powerful automation and productivity tools to meet the challenges of managing your worldwide safety information. Oracle AERS supports the capture, management, reporting, and analysis of serious adverse event and product compliance cases for all medical products including drugs, medical devices, vaccines, biologics, and gene therapies from all clinical and spontaneous sources.

### **Easy to Use, Easy to Administer**

Oracle AERS was designed by industry professionals to be easy to use for all users. The intuitive interface provides powerful functionality at the touch of a button. Each subsystem includes a navigator panel to provide overall context. The AERS graphical user interface provides an interactive presentation of key case information, allowing users to visualize the case elements and understand the holistic case picture. Configuration and administration is performed through the use of validated screens and simple end-user tools.

Case ID: 2006S1000165  
 Case Type: Spontaneous  
 Display Options:  
 Event:  All  Serious  
 Product:  All  Suspect  
 Suspect Product: SASPRIN  
 Event Term Level:  RPT  
 Product Term Level:  RPT  
 Narrative:  RPT  
 Company:  Company  
 PT:  PT  
 LLT:  LLT  
 Trade Name:  Trade Name  
 Company:  Company

Category	Item	From	To	Duration
<b>EVENTS</b>				
- Unk/UnExp	headache	30-SEP-2006	30-NOV-2006	62 DAYS
- Unk/UnExp	hives	30-SEP-2006	30-OCT-2006	31 DAYS
- Unk/Exp	myocardial infarction	30-SEP-2006	30-SEP-2006	1 DAYS
<b>PRODUCTS</b>				
- Suspect Drug	ACVIL	30-SEP-2006	30-SEP-2006	1 DAY(S)
- Suspect Drug	SASPRIN	01-SEP-2006	30-SEP-2006	30 DAY(S)
- Suspect Drug	XUMALITE	30-SEP-2006	30-SEP-2006	1 DAY(S)
<b>Seriousness Criteria</b>				
Narratives				

**Figure1. AERS Graphical User Interface**

## Industry Knowledge

Extensive experience in the clinical and safety industry has been incorporated into the Oracle AERS application. AERS helps ensure that your organization maintains strict compliance with current regulations and emerging industry guidance, and the solution meets E2B interchange standards and local electronic submission rules. Case capture, management, analysis, and reporting features all include an understanding of safety data and the safety process in order to facilitate active safety surveillance and pharmacovigilance.

## Case Management

Oracle AERS has a powerful set of case management features. It is built on a flexible, embedded workflow engine that enables customers to tailor workflow so important cases are handled on an expedited basis. AERS includes a comprehensive suite of data consistency checks and an online discrepancy management system to manage any data issues identified in your cases. Users can create and save queries and case lists for use in ongoing safety surveillance.

## Query

Oracle AERS' powerful query module delivers quick and easy answers to complex regulatory and safety questions, provides product surveillance, and protects your products and product pipeline. The query-by-example subsystem is an integral part of the application - no more relying on external ad hoc tools to find the cases you need. The query subsystem allows users to build complex queries involving any combination of the more than 800 case data elements stored in Oracle AERS, without any programming. Queries can also be extended outside of the AERS data to external sources such as clinical trials data, manufacturing details, lot information, product quality information, or other safety repositories. All queries can be saved, documented, parameterized, and reused as necessary. This enables you to build a library of frequently used queries that can be run by any authorized user.

## Reporting and Tracking

Global biopharmaceutical, vaccine, medical device companies, and CROs may process many thousands of adverse event cases per year. Generating and processing the required reports is a time-consuming process. To significantly increase productivity, Oracle AERS provides a powerful automated report generation and

distribution feature, so reports based on your user-defined rules can be automatically generated at your configured time interval, and optionally distributed by email to recipients such as trading partners, investigators, ethics committees, and your local offices.

Oracle AERS includes a full complementary set of international, expedited, and periodic regulatory reports, as well as a variety of statistical reports, including MedWatch 3500a, CIOMS I, NDA Periodic, PSUR, IND Safety Update, Annual Safety Report, Yellow Card, BfArM, MedWatch for Device, VAERS, MHLW forms 1 and 2, and many more that help organizations comply with changing regulations in today's safety environment.

### **Electronic Interchange of Safety Data**

Oracle AERS provides a highly flexible, comprehensive solution for importing, exporting, and submitting case safety reports. AERS meets E2B standards and local rules for electronic submission to the U.S. Food and Drug Administration (FDA), Japan's PMDA, and the EMEA and EU countries.

### **Signal Identification and Safety Surveillance**

Oracle AERS includes many features for performing safety, surveillance, and signal identification. These features include increased frequency reporting, which identifies increased frequencies of adverse events for a product over two time periods; safety surveillance queries to identify cases requiring surveillance; and powerful, fully integrated visualization and ad hoc reporting tools.

Only AERS is integrated with QScan, DrugLogic's workflow-based analytical tool for identifying, analyzing, and resolving drug safety risks in conjunction with public safety data. AERS pharmacovigilance users can now immediately visualize their case data in QScan and utilize QScan's powerful data mining and signal detection capabilities to focus on the cases of most interest. In addition, drug safety teams can establish thresholds for automatic safety signal detection, receive alerts when thresholds are reached or exceeded, and assess their case information using data mining tools for statistical analysis.

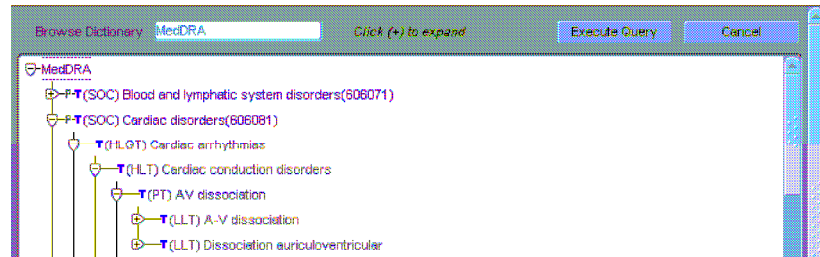
### **Product Repository**

Tracking the details of all of your products is an integral part of managing their safety profile. Oracle AERS offers a robust repository that stores and tracks the details about each of your products. It stores approval history information for all products for automated report distribution, maintains complete product labels for automated derivation of expectedness for each product and event, and manages details for lot reviews to allow searches for hot lots and other quality trends. Additionally, AERS maintains exposure data for every product and derives denominator data for use in its pharmacovigilance reports and functions.

### **Integration**

Oracle AERS provides integration with legacy and commercial application systems, as well as bolt-on application extensions through the use of open APIs and secure database views.

AERS is integrated out of the box with Oracle Thesaurus Management System. Users are able to easily code dictionary terms or browse your dictionaries via the AERS interactive coding form. Multiple active dictionary versions are supported, enabling you to control the version to which you are coding.



**Figure2. AERS Interactive Coding Form: Browse Dictionary**

Oracle AERS includes advanced functionality for integrating and reconciling data with Oracle Clinical. This includes shared metadata with Oracle Clinical, shared study management data, shared patient data, and shared dictionaries and coding, designed to be consistent with regulatory authority requirements. AERS includes a comprehensive solution for clinical data reconciliation, which actively manages the reconciliation lifecycle of each clinical case, automates the clinical and safety data comparison, and tracks the status and resolution of each discrepancy.

### **Configuration and Support**

International safety and pharmacovigilance regulations are subject to continual change. Oracle AERS provides the tools to tailor the application to your specific needs, whether sending or receiving information, without programming. All Oracle AERS customers have a seamless upgrade path, as Oracle enhances the software with additional features and functionality to accommodate regulatory changes.