

ORACLE ADVERSE EVENT REPORTING SYSTEM

OVERVIEW

- 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 compliment 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 allows you to monitor safety issues and incidents over time
- Full integration capabilities with other OLS Applications, including Oracle Clinical and Oracle TMS
- Capture and display data in user's local language
- Robust product repository, including product label maintenance facility
- Full implementation and training services available

Oracle Adverse Event Reporting System (AERS) is a comprehensive solution for product safety monitoring and compliance, and an integral part of the Oracle Life Science Applications suite. With its unparalleled integration with Oracle Clinical and Oracle Thesaurus Management System, Oracle AERS provides the highest quality and the most functionality of any adverse event reporting system.

Industry Challenges

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

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 complaint 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 the user 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.

The screenshot displays the 'Graphical Overview' window for Case ID: 2006S1000165. The case type is 'Spontaneous'. The interface includes a 'Display Options' section with filters for Event (All, Serious), Product (All, Suspect), Event Term Level (RPT), Product Term Level (RPT), and Narrative (RPT). The 'Suspect Product' is set to 'SASPIRIN'. The date range is from 01-SEP-2006 to 30-NOV-2006.

Category	Item	From	To	Duration
EVENTS	- 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
PRODUCTS	- Suspect Drug ADVIL	30-SEP-2006	30-SEP-2006	1 DAY(S)
- Suspect Drug	SASPIRIN	01-SEP-2006	30-SEP-2006	30 DAY(S)
- Suspect Drug	XUMALITE	30-SEP-2006	30-SEP-2006	1 DAY(S)
Seriousness Criteria				
Narratives				

Figure 1. AERS Graphical User Interface

Industry Knowledge

Extensive experience in the clinical and safety industry has been incorporated into the Oracle AERS application. AERS helps to ensure that your organization maintains strict compliance with current regulations and emerging industry guidance. Oracle AERS meets E2B standards and local rules for electronic submission to the FDA, Japan's PMDA, the EMEA and EU countries. 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 the most powerful set of case management features in the industry. It is built on a flexible, embedded workflow engine that allows customers to tailor the workflow so that important cases are handled expeditiously. Oracle AERS includes a comprehensive suite of data consistency checks and an online discrepancy management system to manage any data issues identified in your cases, and allows users to create and save queries and case lists for use in ongoing safety surveillance.

Query

Oracle AERS's powerful query module gives you 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 as 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 over 800 case data elements stored in Oracle AERS, without any programming. Queries can also be extended outside of the Oracle 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 re-used as necessary. This allows 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 the required reports, or 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 that 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, complement 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 an organization comply with changing regulations in our safety environment today.

Electronic Interchange of Safety Data

Oracle AERS provides a highly flexible, comprehensive solution for importing, exporting, and submitting case safety reports using the E2B interchange standard. Oracle AERS

meets E2B standards and local rules for electronic submission to the FDA, Japan's PMDA, 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.

Oracle 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. Oracle 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, and it maintains complete product labels for automated derivation of expectedness for each product and event, and it manages details for lot reviews to allow searches for hot lots and other quality trends. Additionally, Oracle AERS maintains exposure data for every product, and derives denominator data for use in its pharmacovigilance reports and functions.

Integration

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

Oracle AERS is integrated, out-of-the-box, with Oracle TMS. 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.

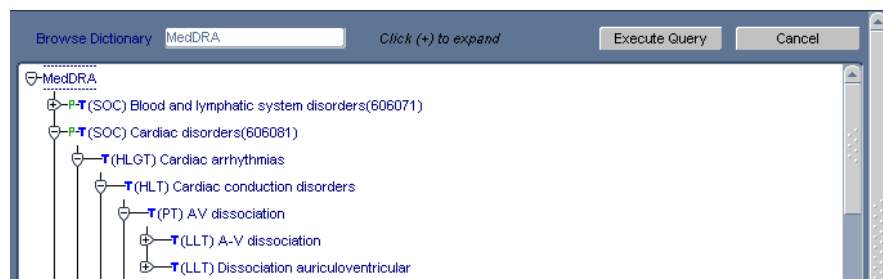


Figure 2. AERS Interactive Coding Form: Browse Dictionary

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 requirements of regulatory authorities.

Oracle 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.

Implementation and Training

Oracle's team of experienced implementation consultants offer both full and fast-track, fixed-priced implementations. Oracle can help you manage the entire implementation process from project planning, to data conversion. We can provide a validation suite that lets you perform a rapid, and complete, system validation, and get up and running in a matter of weeks. Oracle also provides training courses for end-users and system administrators.

More Information

http://www.oracle.com/industries/life_sciences.

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