

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

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

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.

Contact Us

For more information about Oracle Argus Dossier, please visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.



Oracle is committed to developing practices and products that help protect the environment

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