

## ORACLE HEALTH SCIENCES PHARMACOVIGILANCE OPERATIONAL ANALYTICS

ORACLE HEALTH SCIENCES  
PHARMACOVIGILANCE OPERATIONAL  
ANALYTICS ENABLES LIFE SCIENCES  
COMPANIES TO IMPROVE DRUG  
SAFETY COMPLIANCE BY PROVIDING  
VISIBILITY INTO THEIR OVERALL  
SAFETY CASE PROCESS.

### KEY BENEFITS

- More times access to information
- Improved case lock compliance
- Improved safety case processing efficiency
- Insight into operational effectiveness

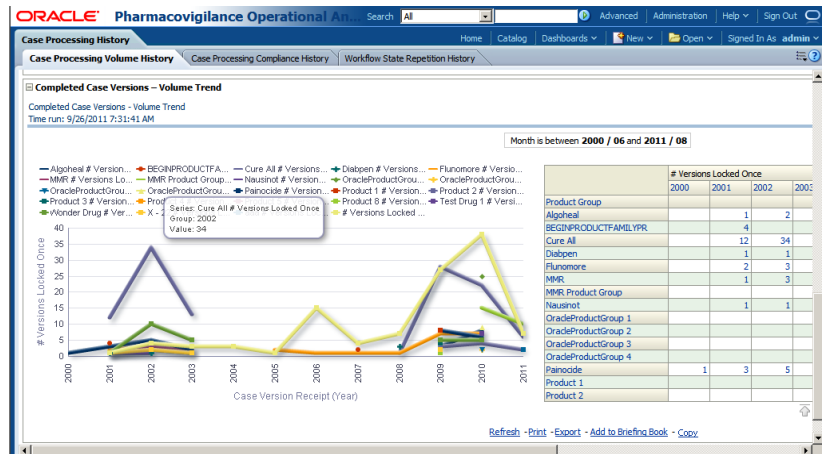
*The comprehensive safety analytics solution with out-of-the-box Oracle Argus Safety integration*

### Doing More With Less

As regulatory requirements and case workloads increase and budgets decrease, it is critical that key executives, drug safety managers, workflow managers, team leaders and case processors have visibility into the safety organization's workflow – from case intake to case lock. This enables the highest quality monitoring and supports meeting regulations.

Oracle Health Sciences Pharmacovigilance Operational Analytics (OPVA) is a comprehensive analytics solution that provides pharmaceutical manufacturers and CROs with timely, fact-based insight into their safety data collection and case processing workflow to bolster productivity and reduce costs.

By proving content that is personalized, relevant and actionable, the solution enables more timely access to business critical information, improved site and staff productivity, and increased safety case processing effectiveness to aid in regulatory compliance.



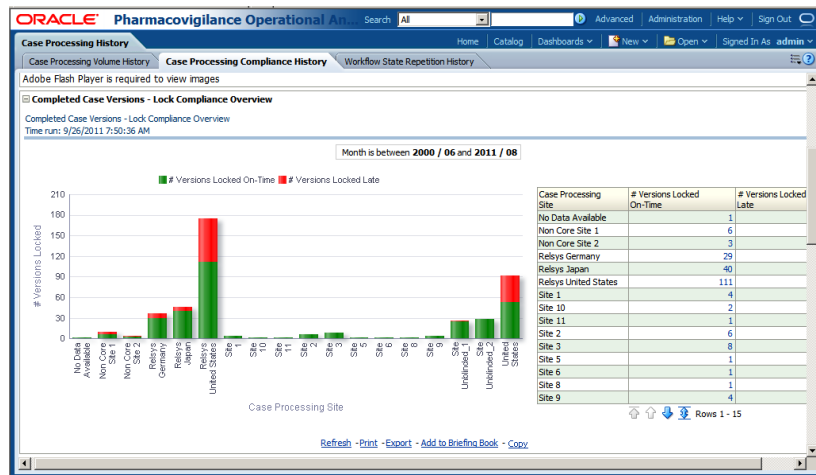
### More Timely Access to Information

Oracle Health Sciences Pharmacovigilance Operational Analytics provides executives and drug safety managers with increased visibility into their safety case processing operations, enabling them to identify workload and compliance issues sooner and make timely, informed business decisions.

It allows a comprehensive view of post-marketed and clinical trial safety cases across all levels of the organization. Drug safety managers receive direct information on the efficiencies of safety case processing, and workflow managers gain insight on how to optimally balance workloads to ensure that cases are locked on time. Executives and compliance managers can measure progress across all sites to quickly identify underperforming areas which may benefit

from additional training or staff augmentation. In addition, the solution offers detailed, real-time as well as retrospective trend analysis of workflow cycle times to help meet both internal and external service-level agreements.

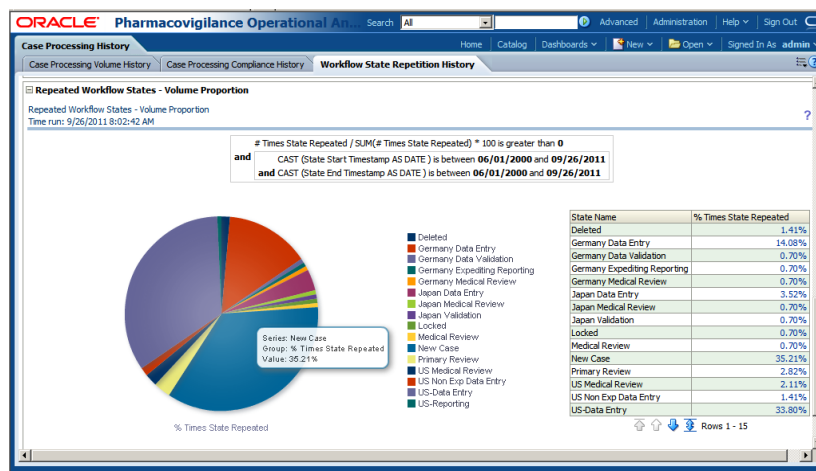
With Oracle Health Sciences Pharmacovigilance Operational Analytics, life science companies and CROs can holistically review and manage all case data workflow processes in their global safety system. Pharmacovigilance organizations can identify non-compliant, sub-optimal and high-load case processing sites and teams to better focus resources and training, while reducing safety case processing time to help ensure compliance.



### Improved Staff and Site Productivity

Safety case processing staff and site productivity can be significantly optimized with greater insight into workflow metrics and site performance using Oracle Health Sciences Pharmacovigilance Operational Analytics. It empowers workflow managers and operations managers to better focus resources, balance workloads and reduce compliance issues.

Drug safety managers and team leaders gain rapid visibility into how their groups are performing against defined targets. By remotely monitoring these key performance indicators, managers can target which teams or sites should be prioritized for additional training. Such proactive monitoring can lead to increased compliance through focused quality improvements and rebalanced workloads.



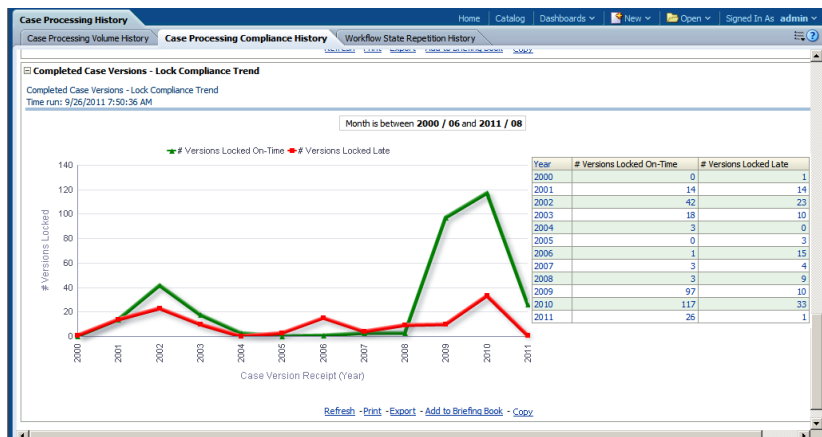
**ORACLE HEALTH SCIENCES  
PHARMACOVIGILANCE  
OPERATIONAL ANALYTICS  
INTEGRATES WITH:**

- Oracle Argus Safety
- Oracle Business Intelligence Suite Enterprise Edition Plus
- Oracle Data Warehouse Administration Console
- Oracle Access Manager
- Oracle Database Enterprise Edition
- Informatica PowerCenter

**Increased Quality and Compliance**

Life science organizations require systems that can improve the quality and timeliness of safety case processing and reporting, thereby reducing compliance risks for both post-marketed and clinical trial pharmacovigilance data. Oracle Health Sciences Pharmacovigilance Operational Analytics provides this capability for pharmaceutical companies and CROs.

It delivers a rich set of prebuilt reports and role-based dashboards providing detailed key performance indicators across products, studies, and sites. Users can quickly gain an understanding of current safety case processing workloads as well as retrospective trends. The simple, intuitive UI empowers users to explore workflow management information and take action to increase case processing resources to address possible compliance risks, balance the workload through effective workflow management, or consider process change or targeted training through cycle time analysis.



**Insight Where and When You Need It**

The powerful web client facilitates access to dashboards, reports, and ad hoc reporting through a simple web browser. The latest release of Oracle Business Intelligence Enterprise Edition provides support for the Apple iPhone and iPad, enabling mobile users to access the latest performance management information on the road. Additionally, integration to Microsoft Office enables users to consume rich datasets in the tool of their choice.



### Faster Implementation, Lower Risk, Better Business Results

Providing actionable insight to safety case processing metrics requires a powerful analytic solution. However, most business intelligence solutions are costly, take a long time to implement, and are difficult to modify when business requirements change. In contrast, Oracle Health Sciences Pharmacovigilance Operational Analytics is a prebuilt solution for fast deployment at a lower cost, with a lower risk, and with better business results. The solution includes prebuilt data models, prebuilt Extract-Transform-Load programs sourcing from Oracle Argus Safety, and around 200 business attributes covering measures, dimensions, aggregations and calculations of workflow metrics. This out-of-the-box platform, combined with a highly intuitive ad hoc report builder, enables users to easily customize and extend dashboards and reports very quickly without burdening IT organizations.

### Reduce Project Risk and Cost with Oracle Consulting Services

Consultants from Oracle Health Sciences are part of a global consulting organization with extensive domain expertise and in-depth experience implementing Oracle's healthcare and life science solutions. Oracle's consultants complement Oracle Health Sciences products to provide a comprehensive solution. They can help organizations:

- *Reduce project risk and improve quality* with Oracle's distinctive resources and expertise
- *Lower total cost of ownership* with Oracle's complete solution
- *Realize faster time to business value* by leveraging Oracle's unique library of consulting assets and accelerators

Oracle Health Sciences' consultant team is 100% dedicated to Oracle Health Sciences products and has many years of experience implementing these healthcare and life science solutions. It is composed of a global team of product experts who leverage their close ties to Oracle's product strategy and development teams, utilize standard Oracle methodologies (Oracle Unified Method aware and certified), participate in numerous international standard-setting bodies (such as HL7 steering committee, CDISC), and embrace a partner-friendly strategy. All the while backed up by the power of Oracle Corporation's global consulting organization. Oracle Health Sciences consultants are uniquely positioned to ensure project success.

### Contact Us

For more information about Oracle Health Sciences Pharmacovigilance Operational Analytics visit <http://www.oracle.com/healthsciences> or call +1.800.ORACLE1 to speak to an Oracle representative.



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**Hardware and Software, Engineered to Work Together**