MANAGING CLINICAL-TO-SAFETY RECONCILIATION WITH ORACLE’S ARGUS RECONCILIATION

Companies are increasingly shifting their focus to a more holistic view of product safety from clinical development continuing through post-market surveillance. The Oracle Argus Safety Suite is an integrated platform designed specifically to address the life sciences industry’s complex pharmacovigilance requirements. Oracle’s Argus Reconciliation, a component of the Argus Safety Suite, helps life sciences companies simplify the cumbersome clinical-to-safety reconciliation process.

**Improved Operational Efficiency**

Inconsistent data between disparate clinical and safety systems can lead to false conclusions about the safety profile of a drug. Reconciling this pharmacovigilance information across departments is a significant challenge. Life sciences organizations spend significant time and resources to overcome this data silo challenge by performing manual quality checks.

Argus Reconciliation reduces the burden of this process by reconciling drug safety data from clinical data management systems with the Oracle Argus Safety database. It significantly improves productivity by eliminating double data entry and reducing the possibility of introducing errors. Its intuitive and user-friendly graphical interface helps identify discrepancies quickly and easily, helping companies shorten the reconciliation process.

*Interactive Reconciliation Report*

After Argus Reconciliation automatically extracts data from clinical data management systems and reconciles it with the Argus Safety database, it generates an advanced, interactive reconciliation report. This report allows easy visual determination of case-by-case data discrepancies. Argus Reconciliation can also be used to generate full reconciliation reports. For maximum flexibility, comparison and update routines are implemented as database-stored procedures.
Lower cost of reconciliation and pharmacovigilance

The disparate nature of safety and clinical systems forces companies to divert limited resources to redundant tasks such as double-data entry and quality checks instead of focusing on strategic pharmacovigilance activities. This can significantly affect the cost of pharmacovigilance operations.

Argus Reconciliation eliminates the need for data entry and vastly simplifies the process of reconciliation. Because it significantly reduces the number of hours that full-time employees spend on data reconciliation, Argus Reconciliation delivers an immediate return on investment (ROI) to life sciences companies. In addition, pharmacovigilance managers are thus able to focus their resources on valuable drug safety analysis rather than resource-intensive reconciliation.

Integrated Safety and Risk Management

Argus Reconciliation is part of the Argus Safety Suite, an integrated platform that supports end-to-end safety and risk management activities. The Argus Safety Suite offers native risk management capabilities to address regulatory requirements and manage a product’s benefit:risk profile (including reporting automation using advanced conditions, documentation storage, collection of information for advanced visualization and for tracking pregnancy registries.) It can also be seamlessly integrated with signal detection and risk management systems for proactive data mining.

Companies can leverage the Argus Safety Suite, including Argus Reconciliation, to increase linkages across clinical safety and post-marketing surveillance, enabling companies to focus on managing a product’s safety profile.

Reduced 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 health care and life sciences 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 have many years of experience implementing these healthcare and life sciences solutions. It is composed of a global team of product experts who leverage close ties to Oracle’s product strategy and development teams, utilize standard Oracle methodologies (OUM aware and certified), participate in numerous international standards-setting bodies (such as HL7 steering committee, CDISC), and embrace a partner-friendly strategy. All while backed up by the power of Oracle Corporation’s global consulting organization.

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For more information about Oracle’s Argus Safety suite, please visit the Oracle Health Sciences website or call your local Oracle office.