

SGS IMPLEMENTS NEW ORACLE ARGUS SAFETY DATABASE

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SGS has implemented Oracle Argus as its new in-house safety database. The changing pharmacovigilance requirements for processing solicited and unsolicited Adverse Events (AE) inspired SGS Pharmacovigilance and Drug Safety team to seek a new solution for day-to-day case processing and providing customers with effective pharmacovigilance solutions.

PHARMACOVIGILANCE AND CASE PROCESSING

Pharmacovigilance, also known as drug safety, is the pharmacological science relating to the collection, detection, assessment, monitoring and prevention of adverse effects with medicinal products¹. Before a medicine is marketed, extensive clinical studies are conducted. Nevertheless, these studies have limitations due to the strict and standardized conditions in which they are conducted. Some rare adverse effects or adverse events that occur late are often only detected once the medicine is marketed. For this reason, it is necessary to keep monitoring adverse effects throughout the life cycle of a medicinal product.

AE reporting is most commonly associated with pharmacovigilance, and consumes a significant amount of resources. AE reporting involves the receipt, triage, data entering, assessment, distribution, reporting (if appropriate), and archiving of AE data and documentation. For pharmaceutical companies, AE reporting is a regulatory requirement in most countries. AE reporting also provides data to companies and drug regulatory authorities that play a key role in assessing the risk-benefit profile

of a given drug. Through the past decades, validated safety databases were developed in order to help the pharmaceutical industry and health authorities in the process of AE reporting and management².

THE SAFETY DATABASE CHALLENGE AT SGS

For many years, SGS was using the Empirica Trace software from the former Phase Forward organisation that was taken over by Oracle a couple of years ago. After this acquisition, Oracle finally selected Argus Safety as its go-to drug safety and pharmacovigilance solution and stopped further development of the Empirica Trace system. It was this decision in combination with new regulatory requirements that drove SGS to look for a new solution for its management of AE reports.

After a thorough evaluation of the different systems available on the market, Oracle Argus was selected as the preferred system and Perficient as the vendor for implementation and hosting of the database.

ORACLE ARGUS SAFETY

Oracle's Argus Safety is a comprehensive safety database designed specifically to address the complex drug safety and

pharmacovigilance requirements of the life sciences industries. The system's advanced database helps to ensure global regulatory compliance, aid faster and more informed safety decisions, and integrate safety and risk management functions.

Argus provides retrospective and real-time analytics for workflow state, case lock, and expedited report submission compliance to improve the quality and timeliness of safety case processing and reporting. It also reduces operational risks for both clinical trial and post-marketed pharmacovigilance data.

The system offers many useful features that drove SGS's decision to select the system as the new in-house safety database.

MULTI-TENANCY

The multi-tenancy feature in Argus Safety allows multiple clients of SGS to reside as separate and unique tenants in a single database with their data completely segregated and restricted to authorized users.

Multi-tenancy enables also SGS to achieve standard configurations (such as code lists, workflow steps, and user/new client setup) across clients or to

have different configurations for specific clients. SGS can quickly set up new clients based on an existing configuration and authorize users for the new client. Furthermore, SGS users with greater access can view their work across multiple clients, understand their sum of work across clients, and make better decisions.

As a result, SGS can use a single database for many clients, which reduces the amount of hardware needed for an implementation. Fewer patches and dictionary upgrades are required, which decreases the resources necessary to support an implementation.

CLOUD SETUP

Hosting a safety system in a compliant cloud eliminates the need to purchase hardware and hire resources to manage the solution. With increased safety demands, applications are becoming more complex and more difficult to manage. Through the cloud setup, ongoing support is available through the Perficient Help Desk services and business continuity is guaranteed for SGS clients. Most importantly, the cloud allows SGS to focus their resources on their core business of AE processing and management.³

ENSURE COMPLIANCE WITH REGULATORY AGENCIES IN EVERY REGION

Oracle Health Sciences safety experts track regulatory developments worldwide to keep Argus current with constantly evolving regulations. Meanwhile, Oracle safety product strategists sit on both ICH and HL7 working groups and work closely with the FDA, EMA, and PMDA to keep products current and help you easily adapt processes to new regulatory requirements.⁴

Support for import, export, and tracking of ICSRs via the E2B standard helps to ensure cases are reported instantly and accurately. Moreover, the recent Argus Safety 8.0.1 version implemented at SGS comes with new expedited reports (e.g. ICH E2B(R3)) for the reporting of AEs.

Furthermore the comprehensive, collaborative and user-friendly periodic AE reporting encompassing PSUR, DSUR and more reduces the time required to produce periodic submissions while increasing their accuracy.

SGS IMPLEMENTATION

As Oracle's flagship safety system, Argus Safety is trusted throughout the industry for its functionality, reliability, compliance, and ease of use, while continued enhancements to Argus Safety will meet both regulatory and industry's evolving needs.

In August 2016, the implementation process started at SGS in collaboration with the Perficient's expert safety team. Argus Safety, version 8 with multi-tenant functionality was successfully implemented based on SGS's design, configuration, procedures and AE case management workflow specifications. In order to guarantee the maximum support and business continuity to our clients, SGS deployed the system in Perficient's⁵ regulatory-compliant clinical cloud.

Thanks to this collaboration together with Perficient's expert safety team, we are proud to offer the leading safety and pharmacovigilance system on the market to our existing and future clients.

SOURCES

1. The Importance of Pharmacovigilance, WHO, 2002
2. <https://en.wikipedia.org/wiki/Pharmacovigilance>
3. <http://www.perficient.com/insights/guides/2016/enabling-better-safety-decisions-with-oracle-argus-safety>
4. <http://www.oracle.com/us/industries/oracle-argus-br.pdf>
5. <http://www.perficient.com/industries/life-sciences>

Read about SGS's [Regulatory and Pharmacovigilance Services](#).

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WHEN YOU NEED TO BE SURE

