



## Sciformix Safety Cloud

Full Service Private Cloud Drug Safety Solution

# Secure, Validated, Compliant, Proactive, and Hassle-free

The Life Science industry is facing ongoing change such as mergers & acquisitions and increasingly complex regulations, along with the pressure of doing more with less. The result is that many organizations have implemented cost-saving measures while maintaining a keen eye on evolving compliance needs. Oftentimes, however, organizations lack the necessary technology skills and resources, and therefore acquiring external IT capabilities to manage their safety data has become a key strategy.

Implementing new technologies can help companies transform their business and overcome impending industry challenges, however life science companies' are especially reluctant to adopting new technologies due to their perception of risks and costs associated with their adoption. This reluctance is no different, especially in drug safety, with the latest technology trend - Cloud Computing.

However, today most life science companies are managing these risks and turning to cloud technology because it offers them the dual benefit of instant scalability and the business agility to meet their changing needs. It also helps them to transform themselves by embracing innovation and reducing IT costs.

# Sciformix Safety Cloud

Sciformix, in partnership with Oracle, offers a full service validated private cloud single tenancy solution based on Argus technology which enables faster and better safety decisions. This automated and integrated solution allows for easy scientific querying and analytics which improves the quality and efficiency of safety operations. It also enhances compliance with E2B exchange for expedited and periodic reporting, allowing the organization to conduct global case processing which can scale to tens of thousands of annual cases. Sciformix's end-to-end Safety Cloud services include:

1. Technology Platform Services
2. User Services
3. Applications Services
4. Reporting Services

What's unique about our four tier offering is that it's end-to-end - typically vendors offer specialized services in one area such as the technology platform, but not user, application and reporting services. Furthermore, we have functional and domain knowledge in both IT (implementing and maintaining technology) and drug safety business and process operations (delivering comprehensive drug safety and risk management services).



Sciformix has domain and functional expertise in safety Technology, Process and People which is governed by a comprehensive Quality Management System (QMS)

## Technology Platform Services

Sciformix will provision and manage your entire validated Argus drug safety system, including the computer hardware, operating systems, relational database, Argus application software, and the necessary network connectivity. We provide all of the necessary validation services, documentation and any data migrations that may be required. Users will have access to the latest security/critical Operating Systems, Database, Argus application patches, up-to-date Antivirus and malware protection. Third party vulnerability tests are conducted twice annually and all backup and disaster recovery services are included. Accessibility and performance of the system are monitored on an ongoing basis and because the system is deployed on a Tier 3+ data center with secure VPN connectivity between the client and Sciformix Argus application, system and data integrity is always ensured.

## User Services

Sciformix's Service Desk operates on a 24/7 model to support clients requests or issues resolution performed to industry standard service level agreements for meeting safety case quality and compliance requirements. Sciformix's incident management system is based on the ITIL framework and follows a typical Level 1 - 4 support escalation.

- Level 1: Sciformix Helpdesk
- Level 2: Argus Knowledgeable Specialist
- Level 3: Argus experts from Sciformix or Oracle
- Level 4: Oracle Argus Engineering Team

## Application Services

In addition to user support, Sciformix provides services around optimizing the functionality of the Argus application so it can do more i.e. configurations, user administration, enhancements, and updates to the current version of the software release. In addition, sensible point release upgrades to the Argus version are provided.

Sciformix application services include, but are not limited to:

- Study Configuration: Clinical and marketed study configuration with associated reporting rules and templates to support electronic ICSR submission

- User Group and User Access Configuration: Support a client's ability to implement access and permissions across products, studies and partnerships
- Code List Configuration: Customer specific code list configuration
- Workflow Configuration: Customized based on client specific requirements to facilitate simple to very complex case entry, review and approval/submission iterations
- Data migration services: Develop and execute custom plans that reflect unique client legacy environments to facilitate a smooth and minimally disruptive transition to the Sciformix cloud

## Reporting Services

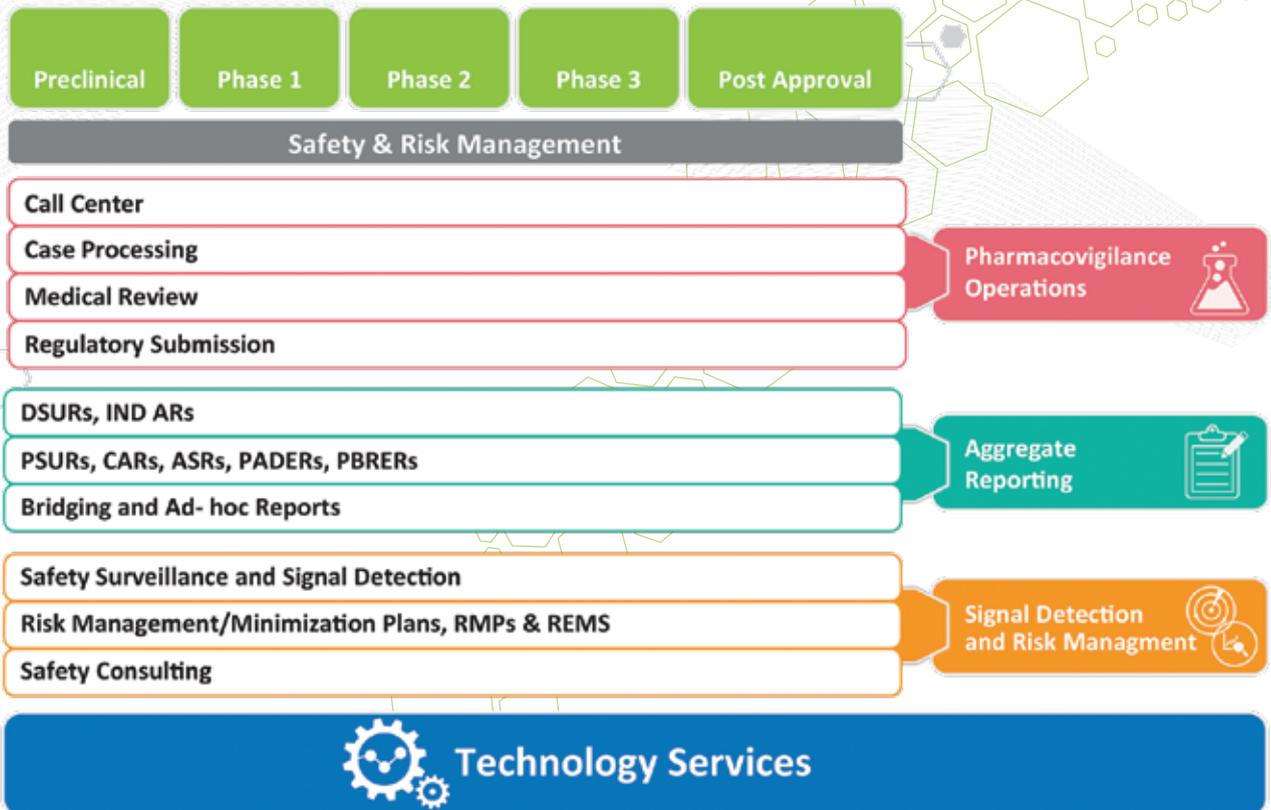
In addition to providing support for native Argus reporting including expedited reports, line listings, case data analysis, periodic reports (PADER, PBRER, PSUR), Sciformix can develop validated custom reports or ad hoc database queries to support time-sensitive data extracts.

## Key Benefits

Why take on the responsibilities of negotiating contracts, supporting and maintaining SW along with end-user support and application services, and back-up and disaster recovery when a specialized provider can do it for you? Sciformix Safety Cloud helps companies:

- Increase their visibility into their entire risk and safety continuum and partner relationships including signal management, ADE and performance analytics
- Improve operational efficiencies through individual and bulk case processing through built in audit trails and validation
- Avoid fines and penalties through risk-profile-driven assessments that meet global submissions standards
- Increase the therapeutic value of their products
- Free up valuable staff and money to focus on core activities of developing products that improve healthcare rather than non-core IT activities

# Sciformix End-to-End Safety and Risk Management Solution



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## Trusted Services. Built on Science.

Sciformix Corporation is a leading scientific knowledge-based organization that provides process, technology and consulting services to the life sciences industry. We collaborate with our clients through the entire product development lifecycle to provide a full range of services from study design to post marketing surveillance and commercialization support.

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