Safety and Risk Management
INTEGRATED DRUG SAFETY
Optimized efficiencies, scalability and product value

In light of the ever-increasing regulatory requirements for product safety, surveillance and signal detection, the continuous monitoring of the benefit-risk relationship continues to dominate the imperatives of life science organizations. A truly integrated approach to pharmacovigilance and risk management can help organizations optimize their practices to meet the market dynamics and facilitate the success of a product in the market.

SciFormix’s integrated operating model provides efficiencies and scalability to sponsors, while enabling them to maintain the value of their products. An integrated solution to safety that includes adverse event reporting, proactive and anticipatory signal detection and global regulatory and writing expertise that is driven by optimized processes and innovative technologies is an absolute necessity.

Transforming Drug Safety to the Next Level

SciFormix’s Integrated Drug Safety solution seamlessly interweaves and synchronizes a comprehensive set of services across all phases of the product lifecycle through a thoroughly mapped and automated process model fixed on a state of the art technology platform. Our scientific experts aggregate and evaluate safety information from all sources, including individual cases, published safety data and competitive products to facilitate evidence-based proactive drug safety decisions. Our holistic approach to risk management provides your organization with updated safety profiles of your developmental and licensed products to assist in addressing emerging safety issues and regulatory requirements in a proactive, comprehensive, efficient and timely manner.

While our approach integrates the skills of our experienced and knowledgeable personnel across all operational levels with your in-house team, we maintain high quality safety data, scalability and predictability by employing optimized and efficient processes, industry best practices, robust metrics and state-of-the-art technology. Our LEAN process and automated operations provide 360° situational awareness through well-defined metrics, seamless information flow, effective monitoring and resource utilization.

People, Process and Technology

SciFormix’s automated enterprise platform, process management systems and proprietary workflow engine enables you to customize processes and metrics to your specifications. Our platform lets you track the process; monitor metrics and extract meaningful reports, all in real time either on your phone, tablet or laptop. Our knowledge management system not only helps us capture, share and reuse experts knowledge across the organization and with our clients, but also implement optimal processes and tools that leverage collected data for better decision making, at all stages.

Clients who have partnered with SciFormix, whether for end-to-end safety solutions or for niche pharmacovigilance services, have benefited from our synergistic combination of procedural expertise, domain knowledge, innovative streamlined processes and robust technology.
Our service teams have supported small, medium and large clients across a broad spectrum of activities ranging from setting up full-function safety systems and processes to taking over a single, well-defined, mature process. Our extensive client base and growth in projects with global clients across all major Therapeutic Areas is evidence of the value.

Sciformix’s Integrated Drug Safety solution offers to not only support your current needs but also provide rapid and flexible adaptation to your evolving needs. We facilitate swift and effective decisions regarding all aspects of drug safety.

SCIFORMIX INTEGRATED DRUG SAFETY SOLUTION

TECHNOLOGY AND INNOVATION

THOUGHT LEADERSHIP AND TRANSFORMATION

QUALITY MANAGEMENT SYSTEM

PROJECT MANAGEMENT OFFICE (PMO)
INTEGRATED DRUG SAFETY
Optimized efficiencies, scalability and product value

Consulting and QPPV Services
• PV strategy and roadmap
• PV process re-engineering and optimization
• Audit and inspection support
• QPPV, Deputy QPPV and Local Responsible Person for PV (LPVRP) support
• Regulatory communications
• Dossier compilation and submission (PSMF, RMP, etc.)

Medical Contact Center
• Adverse events
• Product complaints
• Medical information
• 24x7 coverage, multi-lingual support

Clinical Safety Management
• SAE, SUSAR processing, electronic submission
• SAE reconciliation
• Signal management
• Set-up Safety Assessment Committee (SAC)

Post-Market Safety Management
• Case processing including intake/triage, medical review
• Medical Literature monitoring search set-up, review and processing
• Submission to regulatory agencies (gateway and web traders)
• SDEA (Safety Data Exchange Agreement) support and management

Aggregate Safety Reporting
• Periodic safety reports (development and post-approval)
• Integrated summaries of safety
• Clinical and non-clinical overviews
• Ad-hoc safety issue analyses

Surveillance and Signal Detection
• Ongoing medical review and analysis of cases
• Meta-analysis of published safety data
• Qualitative and statistical signal detection, validation and management

Risk Management and Communication
• Risk management plans (RMPs), risk evaluation and mitigation strategies (REMS), medication guides, patient education materials, Dear Doctor letters
• Post-approval safety studies, patient registries
• Product labels (safety updates)

Technology and Automation
• Technology support for medical call center
• Safety database implementation, support, maintenance
• Safety automation tools

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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.