



**SAFETY
AND RISK
MANAGEMENT**



**TECHNOLOGY
SERVICES**



**CLINICAL
DEVELOPMENT**



**REGULATORY
AFFAIRS**



**REAL WORLD
EVIDENCE AND
MARKET ACCESS**

Corporate Overview

Trusted Services. Built on Science.

Sciformix Corporation is a global scientific process organization (SPO) that partners with life science companies to develop, launch and sustain medical products that aim to improve the quality of healthcare worldwide. 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. Sciformix consistently delivers scientific insight, improved productivity, and high quality results, in every engagement, through a deep understanding of the regulations governing the global life science industry.

Emerging market expansion, growing regulatory pressures, the ever increasing complexity of managing the product lifecycle, coupled with patient and payer pressure to get the safety, efficacy and value of the product right are some of the challenges our clients face. The highly dynamic processes that support these activities must be optimized to deliver accelerated timelines during the development, approval and commercialization of the product. At Sciformix, we employ efficient and mature processes, robust metrics, state-of-the-art technology and scientific expertise to deliver consistent, compliant and high quality results. With us, you will have access to reliable real time data and comprehensive analyses that enables swift decision making.

Client Centric Approach

We work with you as an integrated part of your team and balance your in-house priorities and strengths by bringing in the right skills. We understand that there are no universal solutions and that is why we listen to you and build a fit-for-purpose solution, whether it is a comprehensive offering that spans your entire product lifecycle or a niche area. As our clients would testify, our flexible solutions are not only built to deliver what you need today, but also grow with your evolving needs. No matter what part of the product lifecycle we partner with you on, our distinct combination of scientific expertise, process rigor and technology innovation delivers consistent, reliable and insightful results.

Scientific Expertise

Sciformix's core strength is the expertise of our people and our culture that fosters active collaboration and uncompromising integrity. We inspire trust with our clients through credible partnerships forged by our unwavering commitment to their success. Our healthy mix of thought leaders, SMEs, doctorates, physicians, HCPs and post graduates enable us to provide scientific insight and innovative solutions.

Process Rigor

Our streamlined and agile processes ensure consistent quality, improved efficiencies, adherence to timelines and regulatory compliance. By implementing LEAN methods-based processes, and automation where possible, we achieve seamless information flow that enables effective monitoring, review and control. This model provides us and our clients with real time performance and resource utility metrics so we can continually enhance our delivery, improve quality, manage spikes in volume and deliver predictable outcomes.

Technology Innovation

As our processes become LEAN, our technology infrastructure must support them and our ability to continually improve how we serve our customers. We utilize best-in-class tools to help us research, communicate, collaborate and ensure that we deliver quality product on a consistent and predictable basis. Using our proprietary workflow engine we can customize processes and other vital metrics to your specifications so you can track and monitor your operations and extract meaningful reports in real-time.



Meeting Your Needs

At Sciformix, our sole focus is to provide "best-in-class" scientific services that span the entire product lifecycle from clinical development to post marketing activities. Our areas of specialization can be seen in Figure 1 below.



Safety and Risk Management

Sciformix's holistic approach to risk management allows your organization to proactively manage the safety profiles of your developmental and licensed products, allowing you to address emerging safety issues and regulatory requests in a comprehensive and timely manner. We collect, aggregate and evaluate safety information from all sources, including individual cases, published safety data and experience from competitor products to facilitate evidence-based drug safety decision making.

Our customer-centric approach integrates the skills of our experienced and knowledgeable personnel across all operational levels with your in-house team. We bring to bear our synergistic combination of process expertise and domain knowledge to optimize efficiency and guarantee quality and compliance in all facets of drug safety. Our integrated drug safety solutions not only support your current needs but also provide rapid and flexible adaptation to evolving requirements.

Clinical Development

We help you evaluate, demonstrate and communicate the value of your product through a highly integrated product lifecycle approach.

For instance, we leverage our expertise across the board to provide optimized study design and data analytics and reporting to provide insights that help you make informed decisions across the clinical trial

process. We also specialize in end-to-end services for post-approval studies.

Our comprehensive offerings help maximize market penetration, access and growth potential. Our pool of highly qualified and trained medical experts and scientific writers provide real-time post-launch communications support for your products in different markets.



Regulatory Affairs

Sciformix's end-to-end regulatory affairs services ensure that you deliver a compliant, safe and quality product. We support and provide insight to your regulatory strategy and our expert staff will increase your speed to new market approvals and extend your brand formulations and indications. Our regulatory affairs specialists offer strategic, technical

and operational guidance throughout the entire product lifecycle, from filing of marketing approvals of new products or maintenance of products in regulated and emerging markets, to preparation for regulatory agency meetings and submissions. You can trust our staff to manage the teams, schedules and reporting.

Real World Evidence and Market Access

Real World Evidence (RWE) and Market Access (MA) are increasingly crucial for life sciences companies to ensure patient access and commercial success. Both domains require technical expertise along with strategic insights for informed healthcare decisions and optimal outcomes.

RWE is being widely used to gain an understanding of disease epidemiology, patient journey, real-world use and effectiveness of treatment options, unmet patient needs and the value that products offer in

sub-populations. Sciformix offers end-to-end RWE and late phase services such as study planning, protocol development, clinical study management and reporting.

Market Access requirements span from early product stages (e.g., providing input into R&D, business planning, licensing opportunities, policy landscape) to later stages (e.g., formulary access, tendering and pricing).

Technology Services

Driven by increasing globalization, market consolidation, the burgeoning of digital avenues, and reforms in the regulatory environment, the life science industry has opened up and accelerated its adoption of IT and business process outsourcing. Companies have to reassess their business operations and how they impact productivity, operational costs, quality, and audit readiness.

Technology has become an essential enabler of these goals and has also fostered innovation to support changing business demands.

Sciformix can help companies access clouds of capability, deploy applications and create enterprise portals for improving business performance through operational analytics.



Sciformix Corporation

1500 West Park Drive, Suite 210
Westborough, MA 01581. USA
Phone : 1 (877) 576-5005
Fax : 1 (508) 302-6520
Email : bizteam@sciformix.com

www.sciformix.com

US | EU | India | Philippines

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.