



Service Listing

Solutions and Consultancy

Solutions

We have developed standardized "packaged" solutions which address specific needs of our clients. Thus we are able to ensure rapid response to their needs by our ability to deploy these solutions quickly. These solutions are a combination of qualified people supported by technology and process. Two such solutions are illustrated below.

Literature Case Processing

The only client input required for this solution to be deployed is the product portfolio. We will scan over 4500 peer reviewed journals on a weekly basis including literature databases like EMBASE™, MEDLINE™, Reactions Weekly™. We will identify and process suspect cases based on your portfolio and provide you with an E2B file which can be submitted to regulators or imported into your safety database with minimal additional work. This solution allows you to stay compliant with regulatory requirements as your portfolio grows.

Patient registries

Establishment of patient and pregnancy registries related to special access programs is the key to compliance. Our solution, with its scientific rigor, ensures that the registry objectives are met in a cost effective manner.

Supported by a scientific advisory committee of board certified physicians, this solution complies with all regulatory requirements including protecting patient privacy.

Consulting Services

Our Consulting Services span Drug Safety, Drug Development and Study Design, and Regulatory Affairs.

Drug Safety

Our pharmacovigilance experts have extensive experience in drug safety, in working with regulators to bring new products to the market and in handling regulatory inspections.

They work with you to develop the safety profile of your product through clinical development and then assist you in developing and implementing risk management strategies during and post-approval.

We also help you prepare for upcoming regulatory inspections by reviewing your SOPs and other records. As regulations evolve, we help you assess the impact of regulatory changes and implement them within your organization.

Drug Development and Study Design

Using advanced techniques and proprietary algorithms that support model based drug development, our Biometrics team is able to design an optimal study to ensure that the study outcomes are met in a timely and cost effective manner.

Our statisticians and epidemiologists are also adept at data mining, during drug development for efficient trial design and analysis and in the post-marketing phase for commercialization support.

Regulatory Affairs

Our global team of regulatory affairs experts has worked with US FDA, MHRA, EMEA, MHLW, TGA and other regulatory agencies.

Our experts understand the nuances in regulations across different authorities. They help you develop registration strategies customized to the specific country or region, in emerging or advanced markets.

Sciformix is a knowledge based global service provider for the Pharmaceutical and Biopharmaceutical industry.

We partner with our clients through the entire drug development cycle, to provide a full range of services from study design to post marketing services.

Our expertise lies in using scientific rigor to synthesize knowledge from the deluge of available information and using it, along with our understanding of the regulations, to help our clients make the right decision at the right time.



For more information on how Sciformix Solutions and Consultancy services can benefit your enterprise contact us

Sciformix Corporation

1500 West Park Drive, Suite 250, Westborough, MA 01581

Phone : 1(877) 576 - 5005

Fax : 1(508) 302 - 6520

Mail : ask@sciformix.com

URL : www.sciformix.com