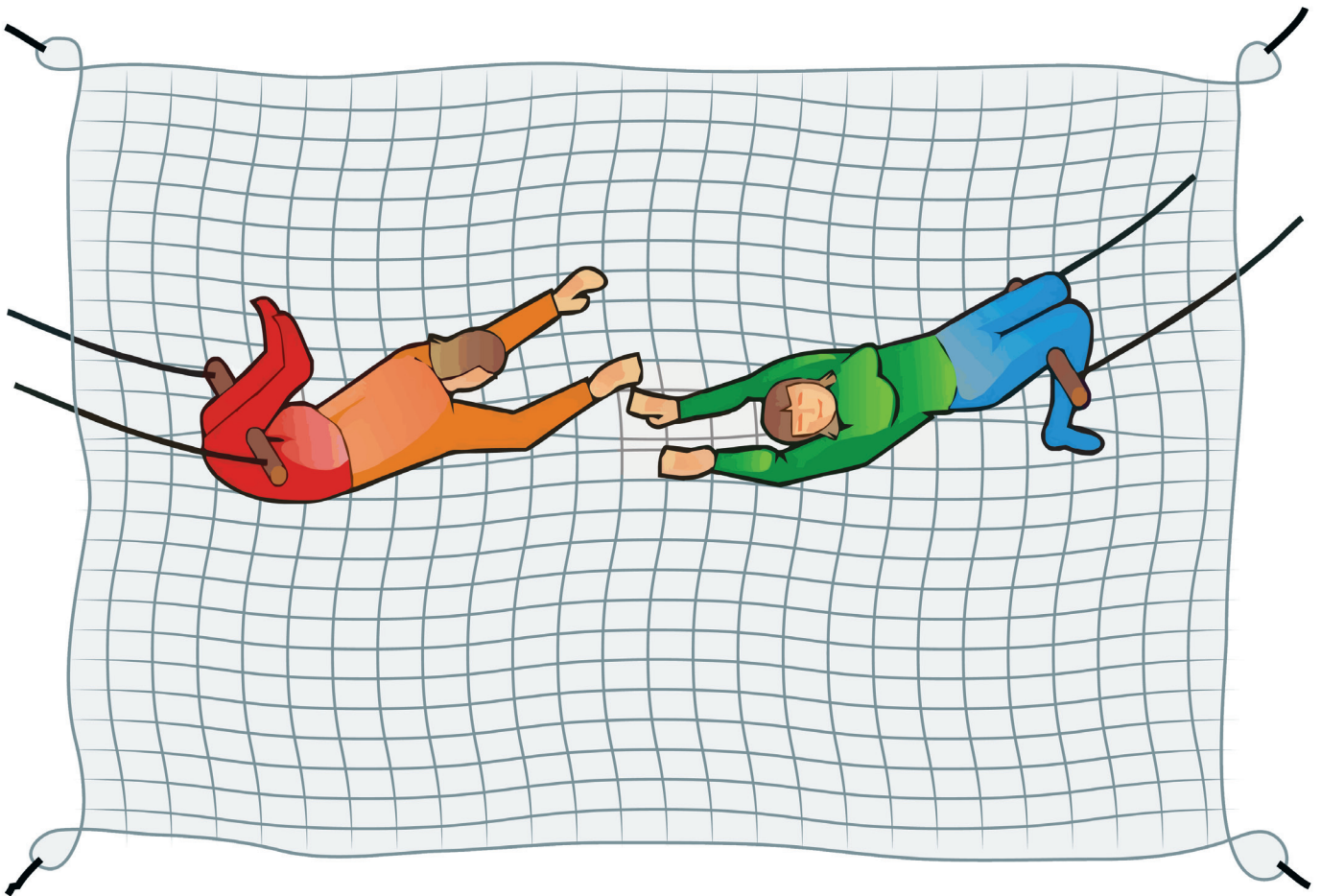


Safety and Risk Management

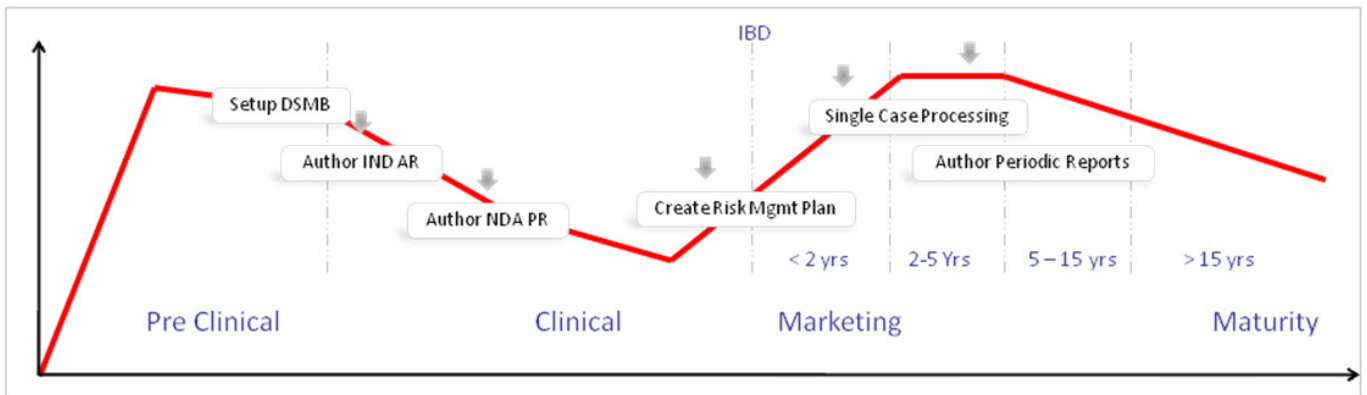
Proactive safety



In a constantly evolving regulatory environment, Sciformix helps you sustain the benefits of your drugs and minimize their risks - Proactively.

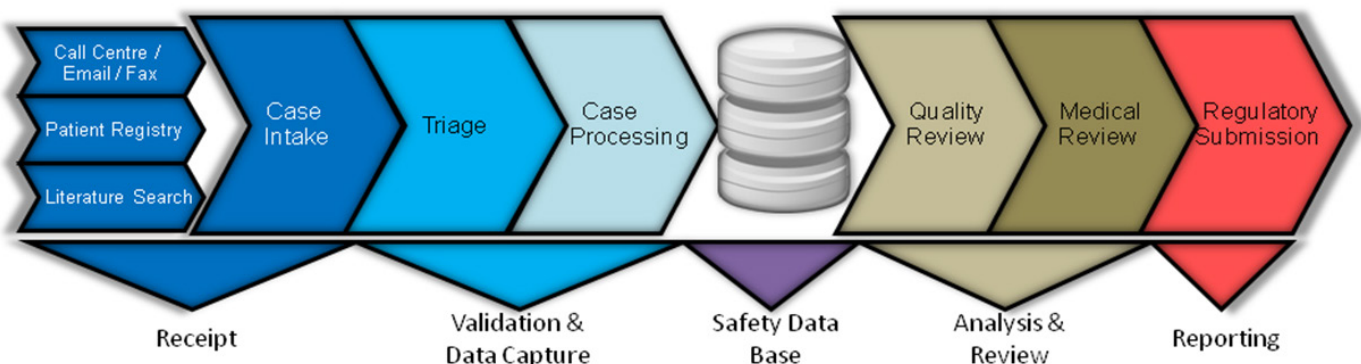
Our Safety and Risk Management services that span the entire spectrum of the drug lifecycle, will help you analyze the benefit –risk profile of your product as well as identify and bridge the gap between peri approval and commercialization.

Our signal detection and signal management services employ both qualitative and quantitative methods to identify signals and anticipate potential risks so as to propose and implement solutions that maximize the benefit of the drug while proactively managing its safety.



Sciformix employs innovative tools, in-house custom safety database and algorithms to capture adequate and accurate data. We perform comprehensive analysis of the data to respond to the increasingly detailed requests for safety information from regulators and stakeholders.

We understand that safety of the drug is largely dependent on the choice of the right population, right administration of the drug and right monitoring. Our safety specialists and regulatory strategists will help you identify potential regulatory concerns and will help you address them comprehensively by developing a Risk Management Plan.





Our safety specialists bring in an external perspective that helps them identify gaps and recommend measures to bridge them. They will help you enhance the benefit profile of your product by recommending appropriate measures, for instance, limiting the use of the drug to a specific population.

Medical Call Center

We operate a 24x7 call center, with live support across geographies from North America to Australia. The call center is staffed with experienced pharmacists and medical graduates.

Medical Call Centre Services

- Adverse events (initial intake and follow-up)
- Product Complaints
- Medical Information requests

Case Processing

Our case processing services include medical review and direct regulatory submissions for different types of cases such as spontaneous, SAEs, literature and legal cases.

Case processing services

- Triage
- Data Entry
- Case review
- Medical review
(including causality assessment)
- Submission to regulators

Risk Management

- Develop RMPs and RiskMaps
- Propose mitigation strategies, develop REMS
- Develop and implement tools for risk management (e.g., education and communication of consumers and HCPs, coordination of patient registries)

Signal Detection

- Periodic review of individual cases in the database to identify potential signals
- Literature review and signal identification during aggregate reporting
- Quantitative evaluation of signals using statistical tools (including IC and EBGM)

Associated Services

We provide access to QPPV services. We also provide associated stand-alone services if clients are looking for help only in these areas.

Associated Services

- Literature Search and Review
- Literature Case Processing
- Coding and Dictionary management
- Narrative writing

Please talk to us and identify how our services can help you better characterize the risk benefit profile of your products.

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