



Service Listing

# Safety & Risk Management

### 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.

Our Medical Call centre services include:

- Adverse events (initial intake and follow-up)
- Product Complaints
- Medical Information (including standard responses to queries)

### Case Processing

Our case processing services (listed below) include medical review and direct regulatory submissions for spontaneous, SAE, literature and legal cases.

We have Eudravigilance certified safety associates who submit cases directly on behalf of our clients. Alternatively, we can also submit E2B files to clients for onward submission to the regulators.

We process individual cases, either using the client's database and SOPs or Sciformix' database and SOPs. The maturity of our processes helps us guarantee over 99% compliance for regulatory submissions.

We have also evolved an extensive quality metrics structure for assessing the quality of case processing and we work with our clients to customize it as per their needs and track it on a regular basis.

Our case processing services include:

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

# Safety and Risk Management

### Risk Management

Sciformix works with clients to develop risk management plans (RMPs) and Risk Minimization Action Plans (RiskMaps) and also supports implementation of the plan.

We have been partnering closely with our clients in the relatively new area of Risk Evaluation and Mitigation Strategy (REMS).

We offer the following services in Risk Management:

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

### Signal Management

We provide signal detection and signal management support, both qualitative and quantitative, including the listed services.

Our Signal Management services include:

- 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)

### Other Services


We provide access to a QPPV for clients who need services of a QPPV. We also provide the following as stand-alone services if clients are looking for help only in these areas.

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

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 Safety & Risk Management services can benefit your enterprise contact

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