Case Study

Pharmacovigilance

END-TO-END PHARMACOVIGILANCE SUPPORT

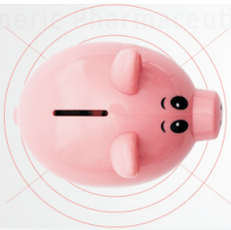
Client Situation

A North American generic pharmaceutical company undertook an evaluation of its processes across the R&D organization to classify activities into core and non-core, with the aim of making certain outsourcing decisions. Risk management and mitigation planning was considered core and had to be retained in-house. Case processing and aggregate report writing was identified as a primarily non-core activity, but given its importance from a regulatory compliance perspective, oversight and control of the process was an important core task to be retained in-house. The client engaged Sciformix to provide pharmacovigilance services for its portfolio of 350+ products across North America, Europe and Australia.

Sciformix Solution

Sciformix proposed a globally distributed delivery model as the solution. PV Subject matter experts (SMEs), one in the US and one in India, were involved right from the initial planning of the transition. A 10-member team of medical and pharmacy graduates was assembled in a period of 6 weeks. The US-based SME worked closely with the client's global PV team to plan and implement the transition. Call center, case processing and aggregate report writing were the activities that were initially transitioned. The Client required that their systems be used and their SOPs be followed. Sciformix prepared Work Instructions to complement the client SOPs and to elaborate on the process to be followed by Sciformix.

- The call center was established as a 20x5 medical call center and now operates 24x7. It provides Medical Information, Product Quality and AE Intake services to the client. Calls are received on a toll-free number in the US, Canada and Australia and are routed to our service delivery center in India. Pharmacists and HCPs were recruited and trained on client's product portfolio and began responding to medical information queries from consumers and HCPs, recording product complaints and recording Adverse Events reported by consumers, pharmacists or HCPs.
- In-depth training on products and the process was provided to associates involved in case triage, case entry, MedDRA coding, authoring case narratives, label assessment, medical review and case validation. All cases received by the client were transitioned to Sciformix from Day 1.
- An experienced PSUR writer was recruited who started authoring a few PSURs and the volumes gradually increased. All responsibilities, including sending out call for contributions, generating line listings, doing literature search and presenting the analysis, were assumed by the Sciformix writer.



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Outcome

- Sciformix processes over 5,000 cases and submits over 150 periodic reports annually.

  Over 99% compliance with regulatory timelines has been consistently achieved.

- The scope of work expanded to include submissions to the regulatory authorities and independent literature case processing. The scope also increased in terms of the support provided to other geographically distributed subsidiaries of the client.

- Operations have completed successful audits

- Greater than 50% reduction in annualized costs over the first year of operations was achieved, while maintaining case quality

- Sciformix is now also involved in activities that were previously considered by the client as being core, like making and implementing Risk Management Plans.

Sciformix is 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 Biometrics service can benefit your enterprise contact us at

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