



## Case Study

# Scientific Writing

## RAPID DEPLOYMENT OF SAFETY WRITING SUPPORT

### Client Situation

A global top 5 pharmaceutical company saw its medical and safety writing needs grow substantially as the result of an acquisition and subsequent re-structuring of its operations. The company had engaged with a large provider for its pharmacovigilance support. However they were looking for specialized support in niche areas, specifically in aggregate report writing. The company engaged Sciformix to provide safety writing support for a part of its portfolio, given the expertise and experience of Sciformix' pharmacovigilance and scientific writing teams.

### Sciformix Solution

The Sciformix team had to collaborate with a globally distributed client team to author the following reports:

- Periodic Safety Update Reports (PSURs)
- Periodic Adverse Drug Experience Reports (PADERS)
- Bridging Reports

The Client's situation was such that they had neither the time nor the resource to provide training to Sciformix's safety writers. The Client made its style guide available to Sciformix and sent a few previous reports. These reports were used by Sciformix' writers to understand the Client's expectations. The first report was assigned in 2 weeks of finalization of the agreement. In addition to a detailed and structured kick-off call, daily email and phone communication was crucial for the first couple of reports that were assigned to Sciformix.

The reports were complex. High volumes of adverse events from the company's safety listings and high volumes of literature articles had to be reviewed, analyzed and summarized. Several primary writers from the Client were involved and a few different medical reviewers were involved. The Sciformix team created a knowledge repository to capture the presentation requirements for different TAs and of different primary writers and medical reviewers, based on the feedback received for each report. This had to be a self-learning process since the Client didn't have resources available for training and mentoring.

### Outcome

Sciformix writing team ramped up very quickly and was able to provide additional capacity to the Client at a short notice. Client feedback on the first few reports has been positive. Thus Sciformix was able to step in at short notice and help the Client achieve aggregate reporting compliance despite the increased load. A 'lessons learnt' document has been prepared by Sciformix. The next step is to discuss these lessons with the Client in order to make the transition and the outsourcing model more efficient. This is especially relevant in view of the subjectivity and individual preferences in authoring PSURs, and the logistics of dealing with tight timelines while incorporating a few previous PSURs in an SBR with a globally distributed Client & Sciformix team.

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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