CASE STUDY

Large Japanese Sponsor Partners with Bioclinica for End-to-End Pharmacovigilance Case Processing

Introduction

Monitoring of adverse event cases is an important step during the post marketing phase (Phase IV) of an approved drug. When a potential adverse event occurs, and is reported to the physician, regulatory agency or sponsor by the patient, it must be reviewed, aggregated with other similar cases in the databases or literature and reported to the regulatory agency in a timely manner.

Situation

A global pharmaceutical company with headquarters in Japan was using the services of another vendor to submit cases that occurred in Japan (domestic) and cases that occurred outside of Japan (foreign cases) to the PMDA. Because of poor quality with this vendor, the company decided to partner with Bioclinica for case processing.

Solution

The company already had a long-standing global relationship with Bioclinica (since 2011) with high-quality results and excellent cost performance in other projects. Bioclinica has drug safety services in which spontaneous cases, literature cases and clinical trial cases are processed, entered and quality checked in Bioclinica's internal safety database. In late 2014 Bioclinica began to process foreign cases for PMDA submission for several studies. By 2015 domestic cases were also evaluated for a specific study.

To transition the project to Bioclinica's processes, an intensive period of planning, training, and monitoring was conducted. End users were certified through case review, to ensure that quality would be maintained.

For this client, the end-to-end case management specifically included:

- Case triage
- Full data entry
- Quality review
- Narrative translation for clinical study cases
- Medical review (by Bioclinica for cases in English)
- Draft for PMDA submission
- Onsite submission
- Reconciliation
- Case archival in the outbound submission tracker (OST**)

***OST is the electronic exchange platform where all E2B files related to PMDA are received and is used as the source for case intake*

A safety control manager facilitated case-related communication between the client and Bioclinica

and conducted inspections,
escalated any non-compliance, and acted as a back-up for the project manager. The safety control manager was fluent in Japanese, was an experienced health care provider, had previous pharmacovigilance experience and was knowledgeable about the Japanese guidelines for good pharmacovigilance practices (J-GVP) and Green Book.

Outcomes

The implementation of case management was successful for this client, with high performance by associates in both Japan and India and excellent communication within the team as well as between Bioclinica and the client. The turnaround time (TAT) and quality metrics according to service level agreement (SLA) were achieved for the last 17 and 14 months, respectively.

Quality targets were exceeded throughout the project. Bioclinica achieved quality of 99-100%, higher than the KPI of 96% as contracted with the client.

The team also delivered beyond their normal capacity, demonstrating their flexibility to meet the client's production requests. In December 2015, the team received an extra 1200 cases (in addition to the normal 1800 cases/month) and delivered all cases within the timeline with 99.4% quality. During Japan's golden week, two days' worth of cases were submitted within one day.

The client could simplify their case processing processes, which reduced costs and shortened the case processing time, which at the same time enhancing their quality and submitting within the contracted timeline. The project was extended by two years in August 2017, and we performed four ad-hoc projects for the same client between 2014 and 2016. We are working with the client to add domestic case processing to the partnership.

Summary

Case processing is an important step during post-marketing drug safety surveillance. Instill confidence in your results and regulatory submissions by partnering with an experienced partner.

QUALITY WAS DETERMINED AS USING THE NUMBER OF FAILED CASES, AS DETERMINED BY:

1 OR MORE CRITICAL ERRORS IN A CASE

2 OR MORE MAJOR ERRORS IN A CASE

3 OR MORE MINOR ERRORS IN A CASE

Monthly Quality % = (Total # of reviewed cases - # of failed cases) / Total # of reviewed cases x 100