CASE STUDY

Gaining Efficiency by Outsourcing Case Processing Activities

Introduction

Pharmacovigilance (PV) plays an important role for patient safety through the collection, recording, analysis, monitoring and prevention of adverse effects with drugs and therapies. This extends to collecting and collating solicited and unsolicited reports of suspected adverse reactions associated with both investigational and marketed medicinal products for human use. One method of documenting these events is the Individual Case Safety Report (ICSR), which is "an individual report of suspected adverse reactions in relation to a medicinal product that occur in a single patient at a specific point of time."1

The volume of these cases ranges from 500/month to as high as 20,000/month. Multiple case reports can be generated for a specific patient, and follow-ups are required for events of interest (e.g., pregnancy cases, overdose, misuse, abuse, medication error, off-label use and occupational exposure). Therefore, considerable resources are required to identify, collect, review and report cases and their related information.

Case reporting can be managed by the pharmaceutical company, or some or all the case reporting can be outsourced. Typical reasons for outsourcing include the need to manage surging case volumes, cost reduction for in-house processing and desire to utilize internal resources for high-end PV tasks such as signal detection, signal management and risk mitigation planning.

Situation

The sponsor, a top oncological pharmaceutical company, was previously performing all PV activities in house but wished to improve their efficiencies in case processing. To do this, the company explored the possibility of outsourcing some, if not all, of their PV activities.

Solution

For seven of their products, the company chose to outsource some of their case processing, specifically non-serious spontaneous cases, non-serious market research cases and serious market research cases. The Bioclinica Pharmacovigilance team was chosen as the outsourcing partner. Because this was the first time the company chose to outsource, they were apprehensive about implementing an entirely new solution. Therefore, we worked closely with the company to add the outsourced services to their existing case processing solution. The workflow collaboratively developed by the company and Bioclinica involves the following: case triage, medical review, final case approval and case distribution & submission by the company; data entry, case classification, assessment, reconciliation and follow-up by Bioclinica.

All data are stored in the sponsor database, and the cases are transferred to Bioclinica once they have been triaged. Following data entry by Bioclinica, the Bioclinica QC team reviews the data entry, including the documents and labels, and the sponsor has the opportunity to review the case again. To help make sure that targets are being met, we maintain an internal case tracking tool.

As with all new processes and working relationships, the one-year transition phase in this project was crucial to ensuring that all parties were satisfied with the workflow efficiency and the quality being produced. At the beginning of the partnership in late 2016, both Bioclinica and the company's trainers underwent a robust training program, and train-the-trainer certification of key staff ensured that the training could continue throughout the project. The efficient team ramp-up included hiring that was completed in advance of the project.

Once the pilot team was signed off by the client, the transition was conducted in a phase-wise process by case categories, starting with simple spontaneous cases in the US and moving to cases in other countries, complex studies, discharge summaries and literature cases.

OUTCOMES

7,300
NEW CASES EXPECTED/MONTH ON AVERAGE

48,000
CASES PROCESSED IN FIRST 7 MONTHS OF 2018

For the first three months, service level agreements (SLAs) were baselined. Quality review was conducted for a larger sample of the cases in the initial months, and as the team's capabilities improved and quality standards were achieved, the number of cases undergoing quality review was decreased. The company also had a backlog of cases that needed to be processed, which was included in the current project. At project initiation, the entire team was dedicated to new cases. Then, a portion of the team was allocated to processing the backlogged cases until completion. Therefore, new and backlogged cases were being processed simultaneously.

Outcomes

During the two-year (and ongoing) outsourcing relationship, the transition process, ongoing training and rigorous quality control processes have resulted in the ability to meet all SLAs (case quality, turnaround time [TAT], follow-up quality) for the continuous four quarters preceding this publication. TATs were met for both regulatory compliance and the aggressive times set by the company.

We established an effective and very collaborative working relationship with the sponsor, developing a solution that provided greater efficiency with regards to data entry and quality control.

OUTCOMES

100%
CASE QUALITY FOR 4 OF THE LATEST 5 MONTHS

Summary

PV activities continue to play an increasingly important role in ensuring the safety of humans exposed to medicinal products in clinical trials and during the post marketing period. Outsourcing case processing tasks to an experienced partner can facilitate full assessment of the drug's benefit-risk profile and allow your team to concentrate on other PV responsibilities such as signal detection, risk mitigation planning and risk management.

1. European Medicines Agency. Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2). July 2017. Available at: https://www.ema.europa.eu/documents/regulatory-procedural-guideline/guideline-good-pharmacovigilance-practices-gvp-module-vi-collection-management-submission-reports_en.pdf