Bioclinica's Pharmacovigilance as-a-Service (PVaaS) Provided Key End-to-End Support to Meet Pharmacovigilance Needs for a Specialty Pharmaceutical Company

Background

Pharmacovigilance (PV) broadly describes the collection, analysis, monitoring and prevention of adverse effects in drugs and therapies. As regulations continue to emphasize patient safety, PV will continue to play an important role in drug development. Staying current on regulatory changes and having the ability to diligently monitor safety-related information can be challenging for companies, especially those without in-house PV expertise.

Situation

A specialty pharmaceutical company focusing on the areas of pain management and addiction medicine decided to outsource their PV support due to growing demands on their limited resources and lack of in-house PV database. The company was also concerned about an outsourcing model from a cost perspective.

Solution

Bioclinica was chosen as the PV provider and instituted their end-to-end PV-as-a-Service (PVaaS) model, which provides PV services and management of the underlying applications and infrastructure. Bioclinica collaborated with the software and hosting vendor to deliver the services, including infrastructure and application hosting, system implementation, application and infrastructure support and business process support.

The transition to Bioclinica occurred in two phases: pilot and go-live. During the pilot phase, a predefined number of activities/transactions was executed, and client feedback was actively solicited. After the success of the pilot, the go-live phase was approved, and the project team executed per the agreed-upon project plan.

Placing importance on quality, Bioclinica worked with the company prior to project initiation to build a quality score card into a Bioclinica-developed web-based quality tracking tool. In addition to Medical Information Call Centre (MICC) support, literature searches, and review activities, Bioclinica established a team of trained and qualified PV resources specifically to process Individual Case Safety Reports (ICSRs) in the Bioclinica-hosted ARISg safety system. Bioclinica also proposed using its own internal workflow processes for comprehensive ICSR management, which was reviewed and approved by the company prior to project initiation. For medical information, Bioclinica utilizes its own fully-hosted Information Request Management System (IRMS) and is a certified partner of the IRMS supplier, Online Business Applications.

Bioclinica provided mandatory global training to selected project team members, based on their specific roles and responsibilities. The program included general PV, hands-on database, voice and accent training and specific project training. Classroom-based and train-the-trainer approaches were also used, as necessary. One-on-one feedback was provided to call handlers during quality checks.

The client engagement manager and project team frequently communicated with the company's key stakeholders, ensuring early identification and timely resolution of potential challenges.

CASE STUDY

Bioclinica's Pharmacovigilance as a Service (PVaaS) Provided Key End-to-End Support to Meet Pharmacovigilance Needs for a Specialty Pharmaceutical Company

AVERAGE
96.2%
QUALITY FOR 2017

KPI OF 90%

AVERAGE
1.12%
ABANDON RATE FOR 2017

KPI OF 5%

Outcomes

Bioclinica has consistently exceeded the company's key performance indicators (KPI) for quality, with an average 96.2% quality for 2017 compared with a KPI of 90%, and call abandon rate, with an average 1.12% abandon rate for 2017 compared with a KPI of 5%, as well as maintaining turnaround times. The initial and refresher training, streamlined processes and issue management approach have played key roles in performance.

For example, the company frequently faced issues with the third-party toll-free number service provider regarding quality and availability of the phone lines, which resulted in consumer complaints. Although Bioclinica already followed the best practice of testing the lines once daily, they took the initiative of testing the lines more frequently for phone line availability and quality. When the availability and quality were not adequate, the company was informed so immediate action could be taken.

This open communication about the challenges and resolutions built trust in Bioclinica as a partner. Bioclinica continues to consult for any in- or out-of-scope PV activities for the company, which has resulted in complete customer satisfaction and expansion of the scope of services offered by Bioclinica, including data migration activity for a recent product, implementation of E2B distribution rules in the ARISg database for one of the company's partners and preparation of Periodic Benefit-Risk Evaluation Reports (PBRERs).

Summary

PV activities will continue to grow in volume and complexity. Trusting an experienced partner to help manage PV requirements can free your team to concentrate on patient efficacy outcomes.

Bioclinica is a global life sciences solution provider that utilizes science and technology to bring clarity to clinical trials – helping companies to develop new life-improving therapies more efficiently and safely. Successful clinical trials require the ability to see key details and uncover hidden insights, and Bioclinica's hundreds of experienced scientific, medical, and domain experts bring unmatched insight across the development lifecycle, from the initial protocol to post-approval. The company's thousands of employees serve more than 400 pharmaceutical, biotechnology and device organizations – including all of the top 20 biopharmaceutical companies and leading CROs – through a network of offices in the U.S., Europe, and Asia.