UBC

Case Study

Pharmacovigilance Data Migration, Database Support and High-Volume Case Processing for Six Oncology Products on an Expedited Schedule

UBC seamlessly assembled a pharmacovigilance program for our client including the migration of over 11,000 existing cases for six products

SITUATION

UBC was selected by a mid-size pharmaceutical company to provide pharmacovigilance services for six oncology products. Four products were in development, and two were in the post-marketing phase in the United States and Europe. In addition to the ongoing studies in the US, the client also established expanded access programs for compassionate use products in various countries. Data from two legacy vendors and multiple sources, including four specialty pharmacies and six license partners, had to be migrated to the new pharmacovigilance system.

Pharmacovigilance support services included:

- clinical trial and post-marketing cases processing
- global expedited reporting
- preparation of periodic safety reports (DSUR, PSUR/PBRER)
- database setup, configuration, hosting and maintenance
- electronic migration of over 11,000 cases from two legacy vendors
- safety regulatory intelligence
- literature review
- signal detection
- project management activities

CHALLENGES

Aggressive timelines for data migration surrounding database lock and data transfer were further compressed due to a natural disaster in the location of the legacy vendors as electrical power and data access were impacted.

UBC's extensive experience in dealing with global regulatory bodies was essential given our clients' portfolio and global footprint. All Suspected Unexpected Serious Adverse Reactions required submission to multiple clinical research organizations for further review by ethics committees and institutional review boards. Cultural nuances and differences required a strategic partner for global regulatory compliance tracking, global safety regulatory intelligence, periodic safety reports preparation and submission.

SOLUTIONS

All staff was secured, trained and ready to go a week prior to program launch. UBC's high-quality training and onboarding process paired senior staff with new staff to ensure rapid knowledge transfer, as well as consistent communication. Multiple groups were formed to cover specialized tasks from intake to submission activities. The rapid development of the team was complete within the client's expeditated timeframes for data migration and case processing.

In addition, shared mailboxes were set up for daily reconciliation of more than 100 emails per day and all potential reports were received and processed immediately within one business day. Our experienced pharmacovigilance team maintained effective communication and collaboration with the client to ensure all regulatory requirements were met.

Our team of experts in global safety, pharmacovigilance, risk management, signal detection alongside our core technology suite resulted in no critical findings during an FDA and Medicines and Healthcare Products Regulatory Agency (MHRA) audit.

UBC'S GLOBAL PHAMACOVIGILANCE SERVICES

UBC combines a depth of experience in safety / pharmacovigilance, risk management, signal detection and assessment with innovative technology systems to provide you with the insights you need to oversee the safety of your product.

In the last three years, we have helped more than 60 companies address their safety needs by implementing and managing over 84 PV programs. Our broad experience includes drug, cellular gene therapy, vaccines, medical devices and over-the-counter products.

Connect with us today to discuss UBC's solutions to meeting your patient safety and regulatory reporting needs.

3 In the past **YEARS**

60 we have supported **COMPANIES**

84 and delivered **PV PROGRAMS**

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