CASE STUDY

Seamless PV Signal Management Enhances Patient Safety and Regulatory Compliance

Comprehensive signal management program for 100 neuro-rheumo/immuno products

SITUATION

UBC was appointed as a Functional Service Provider (FSP) for a leading pharmaceutical company, focusing on their extensive portfolio of established brands within the neuro-rheumo/immuno sectors. For over six years, UBC's dedicated pharmacovigilance (PV) team of 12 full-time equivalents (FTEs), with an additional support team of five signal management experts, has been managing signal detection, validation, and assessment for approximately 100 products. This case outlines the complex challenges and innovative solutions deployed in this critical area of PV.

CHALLENGES

Our client faced several challenges in the design and execution of their signal management strategy:

Workload Variability:

- Managing variable workloads triggered by the detection of safety signals and the requirements of Periodic Safety Reports (PSRs)
- Managing a high volume of products with varying regulatory requirements

Operational Quality and Effectiveness:

- Maintaining standards of signal management efficiency, ensuring both high-quality and effective operations
- Navigating the complexity of diverse PV tasks, including:
  - **Signal Detection:** Conducting semi-quantitative monthly & quarterly analyses of the safety database using our client's process and reports, along with datamining in FAERS with the client's tool, Oracle Empirica
  - **Regulatory Compliance:** Facilitating product renewals, updates to the Company Core Data Sheet (CCDS), and responding to inquiries from health authorities, such as EMA Pharmacovigilance Risk Assessment Committee (PRAC) requests
  - **Risk Management:** Performing thorough benefit-risk evaluations and crafting comprehensive Risk Management Plans (RMPs) to safeguard patient health
  - **Quality and Compliance:** Overseeing the preparation of all types of PSRs

Regulatory Compliance:

- Guaranteeing the prompt identification and communication of potential safety signals to maintain regulatory requirements
- Maintaining compliance with global health authorities, including the FDA, EMA, and other regions

Complex Communication:

- Effectively communicating with multiple client stakeholders of different cultures, including Local Pharmacovigilance Officers (LPOs), to ensure clear understanding and alignment on project goals and company processes
- Managing communication with client representatives from various departments (Medical, Clinical, PV), each with different interpretations of requirements and data

UBC's expertise in PV was sought to address these multifaceted challenges effectively.

SOLUTION

UBC's PV solution encompassed a tailored approach to meet each challenge:

Scalable team dynamics: UBC employs a strategic scalability model, enhancing its dedicated support team of expert scientists and physicians, including contractors who have past experience with UBC, to ensure adaptability to workload fluctuations and maintain high-quality, efficient signal management.

High-quality and efficient processes: Leveraging a dedicated team of FSP Safety Scientists and Safety Physicians enables specialization in product expertise, ensuring in-depth knowledge of each drug's safety profile and familiarity with client processes. This arrangement fosters efficient communication, as the client's safety team and UBC engage seamlessly like colleagues, enhancing collaboration and streamlining safety operations.

Accessible and intuitive technology: In this project, our approach demonstrated significant flexibility by adapting to our client's preferred technological solutions. Traditionally, our team relies on our proprietary tool, UBC Signal Detection, for datamining in large databases. However, for this specific project, we adapted by training our team of Physicians and Scientists to proficiently use our client's tool, Oracle Empirica. In addition, Veeva Vault was used as an electronic document management system for writing PSRs and other documents, to ensure smooth editing & review cycles, as well as standardized and auditable document management.

Specialized talent deployment: In response to the challenge of executing multifaceted PV tasks—ranging from signal detection and regulatory compliance to risk management and quality assurance—the deployment of highly trained Safety Scientists and Safety Physicians with extensive experience in PV is paramount. This strategic approach ensures that complex deliverables are handled with the highest level of expertise, accuracy, and efficiency, directly tackling the intricacies of the PV field.

UBC's integrated signal management and unmatched patient safety & regulatory adherence resulted in zero FDA inspection findings for over 100 products.

RESULTS

The results of UBC's partnership with with our pharmaceutical partner have been significant:

- Successful management of 100+ products with zero findings from FDA inspections regarding the outsourcing model or deliverables
- Significant improvement in signal detection efficiency and reduction in response times to over 90 Health Authority requests
- Enhanced quality and compliance across all aspects of signal management, benefit-risk evaluation, and PSR writing, from signal detection to Dear Healthcare Provider (DHCP) letter writing
- Client satisfaction survey results has revealed a 20% increase in satisfaction scores for operational effectiveness and relationship quality

UBC GLOBAL PHARMACOVIGILANCE SOLUTIONS

UBC combines a depth of experience in pharmacovigilance, risk management, and safety signal detection and assessment with innovative, purpose-built technology to provide you with real-time insights to oversee the safety of your product. In the last five years, we have helped more than 70 companies address their safety needs by implementing and managing more than 78 PV programs. Our broad experience includes drug, cellular and gene therapies, vaccines, medical devices, combination, and over-the-counter products. Connect with us today to discuss UBC's solutions to meeting your patient safety and regulatory reporting needs.

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