PHARMACOVIGILANCE EXPERTISE

WCG Supports Small Oncology Biotech Through Rapid Growth, Saving Hundreds of Thousands of Dollars

WCG expertise enable a small biotech to manage pharmacovigilance, coordinate submissions and reduce delays, dramatically cutting costs and improving efficiency.

CHALLENGES

A small clinical-stage biopharmaceutical company focused on oncology therapies needed to manage its drug safety needs and mitigate risk without additional infrastructure spend. Initially, it had two small Phase II studies running that grew rapidly as additional sites came online. The client needed a partner who could work with its other partners and adapt to their rapid growth. Among its challenges:

Need for safety expertise

The individuals handling safety had a clinical, not a regulatory background. Handling pharmacovigilance, especially the complexity of the SAEs, became an additional burden. The client needed someone to look at safety with a regulatory eye rather than a clinical eye.

Varying workflow

They needed a partner who could adapt to workflow fluctuations, provide advice and rapidly respond to safety data requests.

Coordination around tight deadlines

The client required SAE data collection from its clinical sites. With tight timelines for data exchange, everyone needed to work in harmony. That required careful planning, clear procedures and exceptional communication.

SOLUTIONS

WCG combined and tailored its services to meet the client's specific needs. It became part of the study team, providing pharmacovigilance expertise, domain knowledge and well as project-specific issue management. WCG managed all aspects of the safety-reporting process, following a clear, documented Safety Management Plan (SMP) including:

Case processing and follow-up

- Clinical trial SAE receipt, review and assessment
- Medical coding and narrative writing
- Medical review, quality control and query resolution
- Analysis of similar events
- SUSAR report preparation and communication to sponsor staff.

Report development

- Submission-ready individual reports for health authorities
- Listings for database reconciliation and the preparation of aggregated data reports
- Safety reports sent to investigators through WCG's safety reporting technology platform, Safety Portal.

Safety database

- Set up and configure a fully validated safety database specifically for the client with vendor interface for its management and updates.

Quality assurance

- Including a full set of SOPs, quality control and retrospective review of reports including audit and oversight.

OUTCOMES

Streamlined safety reports

The sponsor was able to distribute safety reports to investigators via WCG's SafetyPortal platform. That ensured the investigator received only what was required, improving document compliance, saving resources and eliminating over-reporting.

Enhanced communication and coordination

Reducing the likelihood of errors and delays across client teams, partners and vendors.

Reduced overhead costs

Contracting with WCG provided a cost-efficient alternative to investing hundreds of thousands of dollars in the people, systems, hardware and software required to build out and manage internal drug safety and pharmacovigilance capabilities. The staffing costs alone, based on two fulltime staffers and a portion of a physician's time would have run close to half-a-million dollars.

WCG further enhanced cost-effectiveness by streamlining processes and coordinating with other vendors.

Time savings

The client has been able to focus more completely on clinical development of its products because WCG reduced the safety-reporting burden and helped streamline the processes. At a minimum, the medical review and senior staff saved 5% to 10% of their time.