Reduced Costs, Better Compliance, More Efficient Trials

WCG's PV Services Smooths Path to Approval for Emerging Biopharma

BACKGROUND

By providing effective safety, pharmacovigilance and risk-management services to small and emerging biopharmaceutical companies, WCG empowers them to effectively manage their resources without a major infrastructure expenditure. This ultimately makes the clinical trial process more efficient, moving more therapies to market sooner.

In this example, the client is a small biotech company conducting a global clinical trial for a novel cardiovascular/metabolic disease therapeutic. The client relied heavily on vendors and CROs to augment its small staff.

The client, unsatisfied with one CRO, brought its pharmacovigilance work in house. Two employees took on the task in addition to their regular responsibilities. They simply managed case processing; they did not look at product safety profiles. Soon, even that became overwhelming. Based on our reputation, they turned to WCG.

The initial scope of work was quite small. They originally asked for case processing and medical review for six clinical programs. That expanded quickly, and WCG adapted.

THE CHALLENGES

As a small, rapidly expanding biotech with sites across the globe, the client faced an array of challenges.

- **RAPID GROWTH:** As the number of participants increased, so too did the number of emerging adverse event profiles to track.
- **LACK OF AN INTERNAL PHARMACOVIGILANCE PROGRAM:** The client did not have a clear view of each area's activities, which meant it lacked a comprehensive picture of the clinical portfolio. Leadership didn't know, for example, who was doing what study, how many more studies were coming online and which type of studies they were.
- **LOOMING DEADLINES:** Data was coming in from sites around the world, and studies were closing

quickly. The client needed to lock the data and resolve outstanding queries promptly and appropriately.

- **MULTIPLE INTERNATIONAL SITES AND VENDORS:** The study ultimately expanded to 80 countries and territories. The client outsourced many of its functions, leading to fragmentation. Different CROs collected data from different sites. Coordination was critical: Vendors needed to work in concert, which requires careful planning and exceptional communication. The client required a partner to adequately manage all the vendors and partners.

THE SOLUTIONS

WCG effectively became an extension of the study team, tailoring its comprehensive suite of safety services to help the client meet its challenges. WCG shared its expertise, providing guidance and counsel as needed.

COMMUNICATION AND COORDINATION: WCG became the single point of contact for the client; the CROs reported to WCG. To keep everyone on track, WCG developed calendars for studies that were closing, then created a calendar for an aggregate report, ensuring a single format despite multiple CROs.

GUIDANCE & SUPPORT: The client relied on WCG not only for what we did, but because they knew they could turn to us for answers. WCG explained the safety profile requirements for each study. WCG's physician oversight ensured the data was in place for them to send to the DMCs. WCG also advised on the frequency for internal data reviews and took on project-specific issue management as needed.

DEVELOPED REPORTS & SUPPORTED SUBMISSIONS

- Explained reporting requirements and provided guidance and review to internal teams and CROs.
- Created submission-ready individual reports for health authorities.
- Managed listings for SAE database reconciliation
- Developed safety-management plans
- Prepared aggregate DSUR/IND Annual Reports (for first two years of engagement).
- Managed SUSAR report preparation and delivery to sponsor staff and CROs.

STREAMLINED CASE PROCESSING OPERATIONS AND FOLLOW-UP, INCLUDING clinical trial SAE receipt, review and assessment and medical coding and narrative writing.

PROVIDED MEDICAL REVIEW, QUALITY CONTROL AND QUERY RESOLUTION.

SUPPORTED PRODUCT-REVIEW ACTIVITIES, including preparing data for Safety Committee meetings, reviewing AE data and providing counsel.

PROVIDED QUALITY ASSURANCE AND OVERSIGHT, including retrospective review of reports and SOPs as well as audit management.

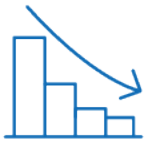
OUTCOMES

STREAMLINED CLINICAL RESEARCH OPERATIONS

WCG identified and cleared backlogs and streamlined operations, allowing the client to achieve each study milestone and meet all deadlines.

BETTER COORDINATION & COMMUNICATION

WCG managed every aspect of the safety-reporting process, from case receipt to assessment, follow-up, triage and submission-ready.



REDUCED OVERHEAD

WCG streamlined processes and coordinated vendors. Moreover, WCG provided a comprehensive, cost-efficient alternative to building an internal PV department.

APPROVAL

The client's initial therapeutic received regulatory approval and is now on the market.