

PV SOLUTIONS

Partnering with WCG Saved Small Biotech Over \$12K Each Month

OVERVIEW

By providing a small immuno-oncology biotech client with focused pharmacovigilance services, WCG improved the pharmacovigilance process, mitigated risk and streamlined safety-related services. Those efforts ensured compliance and allowed the client to more strategically manage its resources, saving approximately \$12,000 to \$15,000 per month.

WCG's comprehensive solution, which included inspection readiness, gap analysis, and consulting and change management, eliminated the need for additional internal infrastructure while lightening the burden on the client's small staff. It also positioned the client for growth by supporting the creation of in-house safety processes, development of product safety databases, and growth and management of an in-house team.

THE CHALLENGE

A small, virtual, clinical-stage biotech with one molecule in early-stage development needed to manage safety and risk mitigation without an infrastructure spend; it could not justify building out an entire pharmacovigilance department. Initially, it had only one Phase I/II study running and focused only on proof-of-concept. That soon expanded with protocol amendments, dosing changes, and additional sites coming online to assist. This led to more subjects and additional emerging adverse event profiles to track.

The management team recognized the need for a partner that could do the heavy lifting and address several key challenges:

- **SPEED:** Immuno-oncology is a highly competitive, fast-moving field. The client needed a partner who could move quickly, efficiently and get to proof-of-concept fast.
- **RESOURCE MANAGEMENT:** Before WCG, one person was managing safety in addition to other full-time duties and was overwhelmed.
- **COMPLIANCE:** Because of the regulated environment and safety landscape of immuno-oncology trials, the biotech needed a partner who could ensure safety compliance across all functional areas.
- **FLEXIBILITY:** It needed a partner as much as a vendor—one who could collaborate, adapt, scale and advise.

The biotech initially turned to a full-service CRO, but they lacked the necessary agility. Cost constraints soon became an issue due to the large volume of safety reports. The company then issued an RFP and assessed six potential vendors, ultimately

selecting WCG to support the PV function. WCG had the tools and solutions the client needed, but it was more than that. WCG had experience in working with small biotechs, none of whom ever got “lost in the shuffle” of larger client work.

THE SOLUTIONS

- 1 PV EXPERTISE:** WCG provided guidance, expertise in oncology and made recommendations along the way. WCG became an extension of the biotech study team.
- 2 CENTRALIZED MANAGEMENT:** WCG managed all aspects of the safety-reporting process, from case receipt to assessment, follow-up, triage and submission-ready. It also submitted safety reports to investigators using WCG’s safety reporting technology that saves time and avoids costly over reporting.
- 3 CUSTOMIZED SERVICES:** WCG tailored its services to address the varying requirements for safety-data delivery. It scaled its offerings to meet the client’s specific needs, allowing it to grow with the client.

LESSONS LEARNED

This partnership yields lessons for emerging biopharma companies with limited resources that nevertheless need to have robust safety solutions in place.

BRING IN A VENDOR EARLY: When possible, opt for a turnkey solution.

LISTEN TO YOUR GUT: Especially in a small company, vendors need to be a good fit. Identify those with the best expertise and then narrow your choice based on how well you will collaborate.

INSIST ON AGILITY: Small companies often have a fluid strategy, so it’s essential to pick a partner who can flex and scale accordingly. A one-size-fits-all “solution” is not a solution.

COMMUNICATE REGULARLY: Once you have a partner in place, set up a weekly standing call instead of relying primarily on email. Changes happen fast, and all parties need to be on board.

“This has been a good journey working with WCG. It’s like any partnership – once you start, you have to be willing to be flexible on both sides. They’ve been really good about flexing with us to accommodate our specific needs and wants as a company. Over time it just gets better and better; I’m just so happy we transitioned when we did because it’s a huge volume of work and I have to hand it to their team for being able to manage that volume.”

—VICE PRESIDENT, SCIENTIFIC AFFAIRS