

# Case Study

## Finding an Agile PV Partner for Early-Stage Clinical Development

WCG Scientific and Regulatory

WCG Vigilare often works with emerging biotech companies to support their pharmacovigilance efforts. These partnerships ensure compliance and allow companies to more strategically manage their resources.

### 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 was focused only on proof-of-concept. That soon expanded to protocol amendments, dosing changes, and additional sites came online to assist. That meant more subjects and more emerging adverse event profiles to track. With only 14 employees, it relies heavily on outsourcing; in fact, the company currently has over two dozen partners. When it came to safety needs, the company's senior management team recognized the need for a partner which could do the heavy lifting and address several key challenges:

- **Speed:** Its therapeutic indication of immuno-oncology is in a highly competitive, fast-moving field. It needed a partner who could move quickly, efficiently, and get to proof-of-concept sooner rather than later.
- **Resource Management:** Because it's a small company, it had to be strategic about using its resources to avoid internal infrastructure build. Vendors need to be on the same page, which requires careful planning and exceptional communication.

*"This has been a good journey working with Vigilare. 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,  
Clinical-Stage Biotech

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- **Compliance:** Due to the regulated environment and safety landscape of immuno-oncology trials, this company needed pharmacovigilance expertise—a partner who could ensure compliance across all functional areas.
- **Flexibility:** It needed a partner as much as a vendor—one who could collaborate, adapt and scale.

### Initial Steps for Partnership

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

In the end, they selected WCG Vigilare to support their PV function due to three primary reasons:

- Vigilare had expertise in working with small biotechs, all of whom never got “lost in the shuffle” of larger client work
- Vigilare’s ability to provide guidance, expertise in oncology, and recommendations along the way was critical, and it allowed them to be an extension of the biotech study team
- Vigilare would manage all aspects of the safety reporting process, from case receipt to assessment, follow-up, triage and submission-ready

### Outcomes and Next Steps

Because Vigilare handles cases in a timely manner, the client has less to worry about and can focus its efforts on developing its therapy. In addition, because of the nature of the partnership, the client can learn from Vigilare’s experience and expertise.

Today, the clinical-stage biotech company is expanding its relationship with Vigilare.

### Lessons Learned

This partnership yields lessons for small pharma/biopharma companies with limited resources who nevertheless need to have robust safety solutions in place.

- **Bring in a vendor early:** When possible, opt for a turnkey solution.

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- **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 "model" 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.
- **Partner for safety:** WCG Vigilare provides its biopharmaceutical/biotech clients with focused pharmacovigilance services in support of marketed products, drug safety services in support of products in development, and related services, such as inspection readiness, gap analysis, and consulting and change management.

## About Vigilare

Vigilare's service solutions result in streamlined operations, giving clients faster access to safety data. Among its offerings:

- a state-of-the-art contact center to meet both in-bound inquiry fulfillment and out-bound patient support services
- direction and management of large safety and risk-management teams
- receiving and processing thousands of adverse-event reports
- patient-support programs; and
- medical-inquiry contacts

Vigilare's comprehensive pharmacovigilance solution eliminates the need for additional internal infrastructure by supporting the:

- creation of in-house safety processes;
- development of product-safety databases; and
- growth and management of a large in-house team.

To learn more, visit us at:

[www.wcgclinical.com/services](http://www.wcgclinical.com/services)