The High Stakes of Pharmacovigilance: Why Specialized Partnership Outperforms the Large CRO Model

By Timothy Roe, *CEO & Co-Founder, M2D Global Life Sciences*
08 April 2026

Preamble

Large, integrated Clinical Research Organizations (CROs) with internal PV practices perform very well in specific situations. For example, they have established systems to handle enormous volumes of post-marketing cases, with strict automated processes that ensure timely compliance with global reporting rules. This setup ensures cost-effective case processing. These teams are staffed with professionals focused on the safety monitoring required of sponsors with both large product lines and high volumes, a sweet spot for the integrated CRO model. Their fantastic successes in this biopharma sector do not always translate to small, emerging biopharma organizations (SEBOs), and many SEBO leaders argue that the large, integrated CRO model is not ideal for clinical-stage, low-volume biopharma, where flexibility and quality are the main priorities.

Modern guidelines from the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) have placed a heavier oversight burden on sponsors. It is no longer acceptable to simply outsource safety tasks. Proactive monitoring is required because a "hands-off" approach carries significant regulatory risk. As a result, sponsors' successful compliance with these increased oversight requirements creates a dilemma for large, integrated CROs that can't or have significant difficulty adapting to sponsors' heightened oversight.

This dilemma presents significant challenges in navigating PV Departments within large, integrated CROs versus dedicated PV Service Providers. Integrated CROs have rigid, unforgiving structures and processes that create a host of PV deficiencies. These deficiencies engender enormous risks and costs for sponsors and their investors. These risks and costs are amplified exponentially for SEBOs.

The observed accelerating deterioration in the quality, regulatory compliance, and flexibility of PV Departments within large CROs over the past decade has highlighted the need for industry-wide awareness. It explicitly highlights their challenges or inability to adapt to the specific needs of SEBOs. Robust comparators exist. Specialized, dedicated PV service providers rapidly address issues that large CROs struggle with.

My role as an executive overseeing a life sciences consulting and advising firm for biopharma organizations of all sizes and stages in their lifecycle gives me extensive insight into the strengths and weaknesses of CRO relationships. The article reflects my formed opinion, and I fully recognize that some readers may not observe the similar traits described. This article explores the distinctions and proposes solutions to enhance the success of SEBO clinical

programs. It is also a call to action, or at least elevates awareness, so we can all raise the bar on performance with our SEBO clients.

Executive Summary

In the complex landscape of clinical development, particularly for rare diseases and specialized therapeutics, selecting a Pharmacovigilance (PV) partner is a decision that affects not only daily operations but also the ultimate viability of a New Drug Application (NDA) or Biologics License Application (BLA).

Large, integrated CROs hold a healthy position where they excel. This primarily lies with post-marketing, high-volume case-processing transactions and established sponsors with extensive, multi-product portfolios. This is their “sweet spot.” They also have a large pool of professionals to draw from, often siloed within the organization.

This article examines the systemic failures often observed when SEBOs partner with a large, integrated CRO for high-stakes clinical trials and specifically for managing their PV system. [4, 5]

Despite intensive and often frustrating remediation efforts exhausted by SEBOs, the rigid, transactional model characteristic of the industry's largest CROs frequently introduces critical risks to study integrity, data quality, and resource management. [8, 9] For specialized clinical programs, transitioning to a nimble, expert-driven PV service provider is not merely a preference but is quickly becoming a regulatory and financial necessity.

The topics in this piece include:

- The Structural Mismatch: Process Rigidity vs. Specialized Needs
- Integrated vs. Dedicated PV Models: A Strategic Assessment
- The Financial Reality: Hidden Costs and Resource Diversion
- Critical Risks to Study Viability
- Conclusion: The Path to Success

The Structural Mismatch: Process Rigidity vs. Specialized Needs

A fundamental challenge in the industry is the cultural and operational mismatch between the agility required for novel therapeutics and the standardized "one-size-fits-all" approach of a large CRO. While large CROs are built for high-volume, post-marketing case processing, this "robotic" approach often fails to account for the unique clinical nuances required by SEBOs. [4, 10]

- **Inability to Adapt:** Large CROs are often siloed and bound by strict established procedures, making them unable to be flexible or adaptable to meet the unique needs of specialized study populations. [5]

- **The "Training Ground" Phenomenon:** Smaller accounts at large CROs are frequently staffed by junior recruits with less experience, leading to higher instability and lower performance. [3]
- **Systemic Turnover:** High turnover rates in case processing layers—which can reach 4x the industry standard—prevent the achievement of consistency and project-specific expertise. [1, 2] Voluntary separation rates in the CRO industry often exceed 30% and have recently been reported at 35%–61% post-COVID. [2, 3]

Integrated vs. Dedicated PV Models: A Strategic Assessment

While large CROs often promote an "Integrated Safety Services" model, SEBOs frequently face significant challenges with this approach. One challenge in particular brings this point to the forefront: the inherent confusion between clinical database (CDB) entries and safety database (SDB) narratives. Through our extensive experience remediating challenges like this, we have identified several reasons this occurs:

- **Operational Silos:** In an integrated model, clinical CRO teams often operate in bureaucratic silos, which is detrimental to efficient study management. Moreover, clinical teams believe they have the wherewithal to perform the required PV oversight and operate the safety governance model, yet this has repeatedly proven insufficient.
- **Role Fragmentation:** In integrated CRO models, role fragmentation often appears as large, multi-functional teams whose members are not always known by the sponsor and who do not assume comprehensive end-to-end responsibility for specific activities. This compartmentalized structure often confuses sponsors about the delineation of roles and responsibilities. Frequently, too many roles are assigned to a single task, leading to a lack of accountability. Conversely, this phenomenon is either absent or infrequently observed in dedicated, specialized PV service providers.
- **Lack of Strategic Control:** Large CROs don't allow SEBOs to maintain strategic control over safety operations and data access because of their rigid processes. A dedicated PV service provider allows a sponsor to maintain strategic control, even as large integrated clinical CROs close out their studies.
- **Lack of Unified Standards:** Large CROs struggle with non-standard processes. For example, using a single, dedicated PV service provider ensures a consistent standard across the company's multiple trials, avoiding the cost of maintaining multiple safety databases.
- **Muddy Reporting:** A large CRO struggles to compile and deliver aggregate data sets. A specialized PV partner simplifies the production of aggregate reports (e.g., DSURs) by delivering a single set of integrated outputs, thereby avoiding the manual compilation challenges and errors common in integrated CRO models.

The Financial Reality: Hidden Costs and Resource Diversion

While large CRO services may appear comparable at the outset, they often require additional funding for PV services that should have been included in the original scope of work. [6, 8] The implications of this include:

- **Diversion of Internal Resources:** SEBOs are forced to "handhold" and micromanage the vendor, effectively performing the work they are already paying for. [7]
- **FTE Impact:** Systemic deficiencies can force a sponsor to deploy nearly double the anticipated internal FTEs (1.89) to manage vendor issues, creating a significant drain on internal productivity. [7]
- **The "Hidden" Budget:** Costs escalate due to unbudgeted change orders and the need for external consultants to rewrite subpar work. Industry data benchmarks the cost of such trial inefficiencies and BLA/NDA delays at approximately $1.5 million per month ($50,000/day for respiratory drugs). [6, 8]

Critical Risks to Study Viability

Systemic failures with large CRO PV systems pose primary threats to the stability and success of clinical programs, particularly regarding the accuracy of filing documentation and regulatory compliance. [9]

- **Data Quality & Regulatory Non-Compliance:** A general malaise in project management at large CROs often leads to "sloppiness" that compromises data quality. This includes late case submissions to regulatory agencies and failure to notify SEBOs when compliance timelines are missed. [9]
- **Study Integrity & Blinded Data Breaches:** A recurring issue with the rushed workload and case volume of large CROs is the unauthorized sharing of restricted, aggregate, blinded data with sponsor medical teams. [10] Such breaches of study integrity are critical and can directly lead to regulatory authorities' rejection of the BLA/NDA.
- **Inadequate Medical Oversight:** Trial safety is often compromised by insufficient attention to specialized medical monitoring. Without deep clinical expertise in the specific patient population, large CROs remain unable or unwilling to apply the specialized assessment frameworks required to accurately evaluate efficacy and safety signals. [9, 10]

Conclusion: The Path to Success

For SEBOs, remaining with a large CRO that is unwilling or unable to adapt introduces substantial risk to program success. [4, 5] Industry data suggest that a more "consultative" partner, one that integrates seamlessly into the sponsor team, can mitigate these risks while reducing total cost of ownership by eliminating the need for constant internal "handholding".

Transitioning to a dedicated PV services provider increases the likelihood of success by focusing on the sponsor's needs, offering flexible processes, providing experienced talent, and leveraging scalable technology to reduce compliance risks. A specialized PV services provider ensures study integrity, protects the BLA/NDA timeline, and supports long-term financial stability.

An additional approach to prevent PV deficiencies from disastrous BLA/NDA harm is to engage senior, independent PV experts to ensure the vendor relationship is meticulously planned and executed with the requisite quality and regulatory rigor. [9]

Sponsor-CRO relationship models are rapidly evolving, as SEBOs and their investors increasingly demand greater specialization and flexibility to accommodate their unique requirements. [11] Consequently, large CROs seeking business for their PV departments must rapidly adapt, or risk being supplanted by dedicated, specialized PV service providers. Executive Management Teams and Boards of large CROs need to come to the realization that for SEBOs, PV is not a transactional function—"it is a strategic asset-protection discipline." [12]

References

1. Burden T. *Successful Leadership Strategies for Reducing Staff Turnover in Clinical Research Organizations*. [Dissertation]. Walden University; 2025.
2. Society for Clinical Research Sites. *Open Letter Regarding Workforce Retention and Inflationary Pressures*. SCRS; 2025.
3. Association of Clinical Research Professionals. *The High Cost of CRO Turnover: Industry Impact and Mitigation Strategies*. ACRP; 2024.
4. WCG Clinical. *Not Like Everyone Else: Unique Challenges for Small & Emerging Biopharma Companies*. WCG; 2025.
5. PharPoint Research. *Building Stronger Relationships Between CROs and Small Biopharma*. PharPoint; 2025.
6. Tufts Center for the Study of Drug Development. Cost of clinical trial delays and inefficiencies. *Tufts CSDD Impact Rep*. 2024;26(1).
7. Genedata. *How Can Data Translation Challenges in Biopharma–CRO Partnerships Be Overcome?* Genedata; 2025.
8. US Department of Health and Human Services. *Examination of Clinical Trial Costs and Barriers for Drug Development*. HHS; 2024.
9. Van Leeuwen B. and Edwards B. The road to pharmacovigilance outsourcing guidance. *Ther Innov Regul Sci*. 2021;55(1):123-134.
10. Clinical Leader. Why site-CRO relationships are so strained — and how to fix them. *Clinical Leader*. Published June 12, 2024.

11. DeCorte, B. L. Evolving Outsourcing Landscape in Pharma R&D: Different Collaborative Models and Factors to Consider When Choosing a Contract Research Organization. *Journal of Medicinal Chemistry* 2020, *63* (20), 11362-11367
12. Drug.Card, *Pharmacovigilance as a strategic asset: leveraging safety data for competitive advantage. 2023*