

# Beyond the Pilot: Scaling the Steep Climb of AI in Drug Safety

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Artificial Intelligence (AI) is no longer a distant promise; it's actively reshaping pharmacovigilance (PV) by driving efficiencies in literature monitoring, signal detection, and aggregate report generation. However, for many small to mid-sized biopharma companies, the promise of AI feels less like a tool and more like a distant summit. We often see smaller safety teams successfully launch a pilot program, only to hit a wall of operational reality when it comes time to scale.

## The Story of the Emerging Sponsor

Imagine a typical emerging sponsor with a promising pipeline and a growing volume of adverse event reports. Their resources are rightly focused on R&D, not massive IT infrastructure. They see the transformative potential of AI to drive efficiencies, yet they face the classic hurdles of the Steep Climb:

- **The Capital Gap:** AI requires significant upfront investment in software and infrastructure. For smaller operations, these costs often compete directly with clinical trial priorities.
- **The Talent Paradox:** Successful AI adoption demands a rare triple-threat of expertise: drug safety, data science, and regulatory knowledge. Finding this blend in a smaller team is like searching for a needle in a haystack.
- **The ROI Lag:** With lower case volumes, the payback period for these massive investments is often too slow to justify the early spend.

Without a clear path forward, these teams risk pilot fatigue, meaning innovative tools are eventually abandoned in favor of manual, "safe" methods that simply cannot scale.

## Navigating the Roadblocks

Even when a system is implemented, the engine room of AI requires constant attention. Smaller teams often find themselves overwhelmed by continuous upgrades, bug fixes, and the ever-present eye of regulatory scrutiny. Integration complexities with legacy systems can negate efficiency gains, while cultural resistance and concerns about reliability can slow internal acceptance.

## Bridging the Gap: The Human-AI Partnership

The transition from a regulatory obligation to a strategic advantage happens when the "how" of AI is humanized. It isn't about replacing the safety expert; it's about giving them a digital co-pilot.

EVERSANA is helping emerging biopharma sponsors transform this complexity into accessibility. By moving away from an owner-operator model to a shared-service ecosystem, mid-sized firms can bypass the trial-and-error phase.



This approach shifts the story from a struggle for resources to a story of partnership:

**Shared Costs, Advanced Tools:**

EVERSANA's shared-service models reduce technology costs, making elite, AI-driven tools affordable for any scale.

**Regulatory Confidence:**

EVERSANA's deep experience with global regulators ensures that systems are audit-ready and compliant with evolving standards.

**Effortless Deployment:**

EVERSANA manages the setup, validation, and continuous support, freeing in-house teams to focus on patient safety.

**Expertise on Demand:**

EVERSANA's access to data scientists and PV specialists allows firms to scale without expanding headcount.

## A New Chapter in Patient Safety

The story of modern PV is no longer about who has the largest IT budget. It is about who can most responsibly harness AI. To date, more than 20 small and medium-sized clients have successfully transitioned to the PV Orchestrate platform, automating literature monitoring and PADER report generation with AI.

By merging human regulatory insight with technical operational expertise, emerging biopharma companies are turning the steep climb of AI into a steady, scalable path toward excellence-advancing patient safety and turning pharmacovigilance into a true strategic advantage.



EVERSANA is the leading provider of global commercialization services to the life sciences industry. The company's integrated solutions are rooted in the patient experience and span all stages of the product life cycle to deliver long-term, sustainable value for patients, providers, channel partners and payers. The company serves more than 650 organizations, including innovative start-ups and established pharmaceutical companies, to advance life sciences services for a healthier world. To learn more about EVERSANA, visit [EVERSANA.COM](https://EVERSANA.COM) or connect through [LinkedIn](#) and [X](#).