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# De-risking drug development: Ex-US clinical trials as a strategic advantage in 2025

The industry faces a significant dilemma in 2025 as it strives to maintain innovation amid growing global instability.

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September 9, 2025

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The global clinical trial landscape in 2025 presents a paradox. On the one hand, innovation is flourishing—with cell and gene therapies, AI-enabled drug discovery, and personalized oncology approaches reshaping the future of medicine. On the other hand, geopolitical tensions, regulatory volatility, and significant changes at FDA have introduced new complexities. Sponsors must navigate these uncertainties with agility, balancing innovation with global strategies that buffer against operational and regulatory risk factors.

In this evolving and complex global environment, a growing number of biopharma sponsors are viewing ex-US clinical trials as a deliberate de-risking strategy—one that safeguards timelines, budgets, and long-term commercial potential. This is not simply about geographical expansion—it's about integrating global trial design into the core development strategy from the outset.

## The evolving US landscape: A source of friction

In the first half of 2025, several structural and political headwinds have made the U.S. clinical trial environment increasingly challenging:

**Regulatory Uncertainty:** The FDA is under increased scrutiny by both political parties, resulting in a more cautious stance on trial approvals and a more measured approach to accelerated pathways. Staff layoffs, leadership departures, and shifting policy are fueling concerns about slower or inconsistent review timelines. While there has been no formal declaration of a slowdown, recent GAO reports and sponsor feedback suggest increased variability in review timelines, underscoring the need for early FDA engagement and well-prepared briefing materials.

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**Healthcare Workforce Shortages:** Persistent understaffing at U.S. trial sites, compounded by economic fatigue and burnout, are impacting trial capacity and data quality. Over 30% of U.S. sites report delays making staff shortages a consistent barrier to timely site activation and enrollment. Most clinical trials are now behind schedule.

**Economic Pressures:** Rising costs—from investigator fees to insurance premiums—are squeezing biotech budgets, particularly for emerging companies. Global trade conflicts and tariff threats add further uncertainty related to commercialization and global supply chains.

**Patent Cliff Anxiety:** As the looming 2026-2028 patent cliff puts pressure on big pharma revenue streams, early-stage innovation timelines are being tightened—leaving no room for regulatory or operational setbacks. This environment increases the strategic value of parallel ex-US trials to avoid bottlenecks in the U.S. system.

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## Ex-US trials: A strategic hedge

Sponsors are increasingly shifting clinical trials to regions like Asia-Pacific, Eastern Europe, and Latin America.  While these geographic shifts often provide cost savings, ex-US development strategies have become a common risk diversification tool.

Key strategic advantages include:

**1. *Regulatory Predictability***

In APAC, especially in countries such as South Korea, Australia, New Zealand, and Taiwan, opportunities for faster start up timelines and science-driven dialogue have gained interest. For instance, Australia's Human Research Ethics Committee/Clinical Trial Notification process remains one of the fastest globally and can enable site initiation within weeks. Political stability and predictable regulatory pathways have created a favorable and attractive drug development environment for both early phase and later phase clinical trials.

**2. *High-Quality, High-Volume Patient Access***

APAC and Eastern Europe provide access to genetically and ethnically diverse patient populations with high disease prevalence, particularly for oncology, infectious diseases, and metabolic disorders. This not only enhances recruitment but also generates globally relevant and representative data.

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**3. *Site Infrastructure & Talent***

Many APAC nations have seen public and private investment in site infrastructure and digital health integration. South Korea, for example, continues to set global benchmarks for centralized clinical trial data systems and tech-enabled site management.

**4. *Geopolitical Insulation***

Compared to the U.S. and EU, many emerging markets have been relatively insulated from political disruptions affecting health policy. This makes long-term trials less vulnerable to regulatory shocks or funding fluctuations.

## Sponsor mindset shift: From tactical to strategic

This represents a proactive, forward-looking shift that builds resilience into the development portfolio.

In 2025, biopharma sponsors are no longer viewing ex-US trials as secondary options or stopgaps. They are building hybrid global development strategies, where ex-US markets carry the weight of speed, diversity, and scalability, while U.S. trials are preserved for registrational and reimbursement alignment.

This shift enables companies to stage investment, de-risking initial development. In a capital-constrained funding climate, this sequencing can preserve runway and maximize investor confidence.

## Building a resilient global portfolio

De-risking doesn't mean decentralizing. It means being intentional and strategic.

The objective is to align trial location and sequencing with both regulatory predictability and commercial objectives, minimizing exposure to single-market risks.

Sponsors should ask:

- Which countries offer the fastest ethics approvals?
- Where can we achieve both patient access and high-quality data with minimal startup delays?
- How can we align early-phase trials with longer-term global regulatory objectives?

Global CROs that understand regulatory, cultural, and logistical nuances across these regions—while maintaining U.S. alignment—are ideally positioned to support this shift.

## The future: Resilience as a competitive advantage

In 2025, resilience and foresight are as critical to success as scientific innovation.

In a world where time-to-market and capital efficiency are everything, ex-US trials provide more than a buffer—they provide strategic leverage. Companies that recognize the value of a global strategy, cross-border harmonization, and early regulatory engagement will not only survive the turbulence of 2025 but emerge stronger.

De-risking through global diversification is no longer a backup plan—it's a blueprint for success.

## About the Authors

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Source: https://www.bioxconomy.com/clinical-and-research/de-risking-drug-development-ex-us-clinical-trials-as-a-strategic-advantage-in-2025