



Going Global: Assuring Supply in a Rapidly Evolving and Increasingly Volatile Clinical Trials Landscape

The globalisation of clinical research is accelerating, with a growing share of trials now conducted in emerging markets across Asia, Latin America and Africa. Venturing into new regions offers clear advantages, including opportunity to reach diverse patient populations, speed recruitment and address areas of high unmet medical need. And while opportunities are plentiful, so too are the challenges of assuring safe, compliant and timely supply to patients.

Extending clinical trial operations outside of the comfort zones of North America and Western Europe often means encountering fragile infrastructure, long and unpredictable transport routes and limited cold chain capacity, all of which can threaten supply continuity. Regulatory complexity and varying import requirements further complicate matters, while new and ongoing geopolitical volatility has shown just how quickly supply chains can be disrupted; affecting shipment timing, security, site access and overall trial operations. Extreme climates, ranging from desert heat to tropical humidity, can add further pressure, increasing the risk of temperature excursions for sensitive biologics and vaccines.

In 2026, embracing the benefits of going global means taking on additional logistical complexity to maintain reliable patient access. Sponsors that plan early and plan often, use real-time monitoring and work with trusted local partners can reduce disruptions and keep trials on track. In today's rapidly evolving and increasingly volatile clinical trials landscape, a resilient and well-managed supply chain is a prerequisite to delivering the right supplies, to the right patients, at the right time and in the right condition.

The Threats to Supply Continuity

One of the primary hurdles in hard-to-reach regions is effectively navigating regulatory and import/export requirements. Across emerging markets, sponsors often face complex documentation demands, varying permit requirements and unpredictable approval timelines. Even when all paperwork is complete, approvals can take weeks and customs delays can hold shipments indefinitely, compromising product integrity and patient access. This complexity is compounded in regions affected by political sanctions or ongoing conflicts, where import regulations can shift quickly and alternative logistics routes may be limited.

Maintaining end-to-end temperature control is another critical challenge. With an increasing number of trials involving biologics, vaccines and sensitive materials, reliable cold chain management is essential. Infrastructure gaps, from limited airport storage to unreliable road networks and/or 'boots on the ground,' can expose shipments to extreme temperatures and heighten the risk of excursions.

Access to reliable, on-the-ground expertise is vital but often difficult to procure. Many regions require local representation for customs

clearance, permit applications, or last-mile distribution. Without vetted local partners, paperwork errors, transport delays, or regulatory missteps can lead to fines, shipment rejections, or product loss. In remote areas, poor road networks, limited courier capacity and extreme weather can further complicate delivery.

Geopolitical volatility adds another layer of risk. The ongoing conflict in Ukraine, along with recent developments in parts of the Middle East, have shown how quickly supply chains can be affected. Restricted airspace, disrupted shipping lanes and sudden security-driven site closures create new challenges for sponsors to navigate.

With patients waiting for potentially life changing IMP, responding with precision and speed to the complex and multifaceted challenges of operating global clinical trials is mission critical. If these challenges are not managed effectively, supply interruptions can delay patient dosing, cause protocol deviations and undermine trial timelines. Sponsors must therefore integrate regulatory diligence, temperature control, local expertise and contingency planning to maintain reliable access to investigational therapies in harder-to-reach regions.

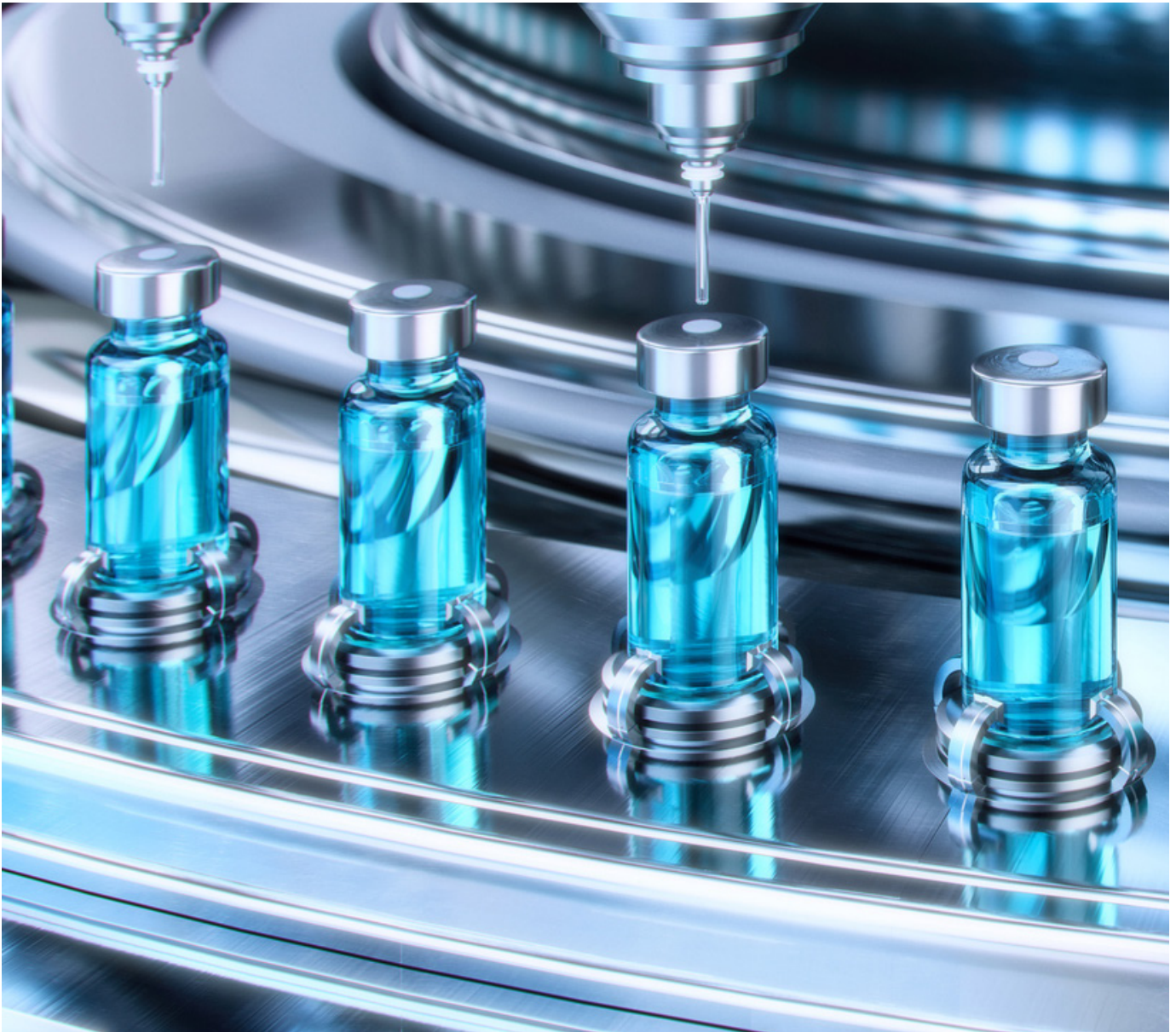
Overcoming Complexity

To achieve this, these challenges must be approached strategically. The first step is ensuring regulatory compliance. Accurate, complete documentation and a deep understanding of country-specific requirements, from ethics approvals to import permits, are key. Planning at least three to six months ahead allows sponsors to define stakeholder roles, identify the Importer of Record, and secure in-country support for smooth customs clearance. Lead times in emerging markets are often longer than in Europe or North America, so early preparation is critical.

Risk assessments tailored to shipment lanes and regions help sponsors build resilience. Contingency measures, such as alternative routes, backup couriers, secondary storage sites and use of direct-to-patient distribution, can mitigate disruptions caused by infrastructure gaps, extreme weather, or geopolitical volatility. Proactive risk mapping also supports compliance audits and informs business continuity planning.

Temperature management is another critical focus. In regions with limited infrastructure, visibility declines once shipments leave manufacturer facilities, increasing the likelihood and reducing the detectability of excursions. Sponsors can reduce risk through validated packaging, phase-change shippers, multiple real-time temperature monitors, GPS tracking and use of end-to-end temperature management systems. Timely monitoring and rapid adjudication help prevent compromised product reaching sites.

Finally, reliable local partnerships make all the difference. An on-the-ground presence helps troubleshoot issues, accelerates customs approvals and ensures compliance. However, it's important



that sponsors vet couriers and logistics providers through quality audits, regular on-site checks and robust contractual agreements to guarantee adherence to GDP/GXP standards. Combining regulatory diligence, proactive risk assessment, robust temperature management and trusted local partnerships enables sponsors to maintain continuous, safe supply to patients in even the most challenging trial environments.

Keeping Patients at the Heart of the Mission

Taking trials global presents significant opportunity but it also introduces complex supply chain challenges. Sponsors expanding into emerging markets face regulatory complexity, infrastructure gaps, limited cold chain capacity and geopolitical volatility, all of which can threaten timely and safe supply to patients.

Effective strategies to mitigate these risks, and keep patients at the heart of the mission, include early planning, regulatory diligence, risk assessments, contingency preparation, real-time, end-to-end temperature management and partnerships with trusted local providers.

By integrating these measures, sponsors can ensure resilient supply chains that maintain patient access, protect product integrity and keep

trials on schedule in a rapidly evolving and increasingly volatile clinical trials landscape.

REFERENCES

1. <https://www.pharmaadvancement.com/drug-development/clinical-trials/growth-of-clinical-trials-in-emerging-markets-and-its-impact-on-pharma-supply-chains>

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