



De-Risking Clinical Trial Supply Provision and Logistics: Key Considerations and Strategies

Executive Summary

In the current clinical trial landscape, supply continuity and logistical efficiency are essential for success, particularly in complex therapeutic areas like cell and gene therapy. Key activities, including forecasting, supplier diversification, and proactive contingency planning are essential risk-mitigation approaches required for streamlined clinical trial operations.

Supply Chain Risk Management

Forecasting

Supplier
Diversification

Logistics
Optimization

Communication

With over 300 active global studies (Pre-clinical through Phase III), support for 250 trials focused exclusively on clinical supply and logistics services, and management of thousands of unique clinical supplies in inventory, Versiti Clinical Trial Services (VCTS) brings proven expertise in maintaining operational resilience—including during the unprecedented challenges experienced during the COVID-19 pandemic. Where others faced critical delays and disruptions, Versiti offers comprehensive solutions that enhance clinical trial efficiency, accelerate timelines, and ensure reliability for diagnostic companies, pharmaceutical sponsors, and specialty/reference laboratories.

Essential Practices for De-Risking Clinical Trial Supply Procurement

1. Forecasting and Planning: Ensuring Supply Continuity

Accurate forecasting is critical to prevent supply shortages or overages, which can compromise trial integrity and impact costing. A balanced approach emphasizes:

- **Data-Driven Planning:** Utilizing historical data, patient enrollment trends, and real-time inventory monitoring to anticipate supply needs.
- **Industry Benchmarking:** Comparing organizational performance, processes and practices against those of leading companies in the same industry to identify areas for improvement and drive a competitive advantage.
- **Agile Operational Forecasting:** Building staffing and resource models that allow for operational agility ensures flexibility in resourcing for fast-paced environments.
- **Contingency Protocols:** Develop pre-defined contingency plans, including alternative shipping routes, backup storage facilities, and emergency distribution strategies, to ensure trial continuity in adverse conditions (e.g., weather events, geopolitical instability).

Proven Reliability – Benchmarking: While the average shipping time for clinical supplies to sites was 3.4 days during the pandemic (Lai et al., 2021), Versiti's agile supply chain management consistently maintained faster, uninterrupted delivery timelines, averaging **2.8 days**.

Proven Reliability – Startup Times: Versiti repeatedly achieves **start up times of just 2–4 weeks** for kitting and logistics setup, significantly faster than typical industry timelines of 2-3 months stated by many clients, enabling sponsors to accelerate trial initiation.

2. Supplier Diversification and Management

A comprehensive supplier management strategy reduces the risk of single points of failure through:

- **Multi-Vendor Sourcing:** Establishing relationships with multiple suppliers across product lines ensures backup options, mitigating risks associated with regional shutdowns or transportation delays.
- **Stringent Quality Controls:** All suppliers are rigorously vetted, focusing on product consistency and quality.

Proven Reliability – Outpacing Industry Challenges: While the COVID-19 pandemic caused widespread shortages and increased lead times for clinical kitting and logistics across the industry, Versiti's multi-vendor strategy helped prevent stockouts and reduced trial delays. Throughout the COVID-19 pandemic, Versiti maintained **100% supply continuity** across essential materials, such as critical collection tubes (serum, plasma), as well as clinical supplies that were needed to maintain oversight of safety evaluation in clinical trials. (Lai et al., 2021).

3. Advanced Logistics Optimization

Efficient logistics are key to timely, reliable clinical trial operations. These include:

- **Real-Time Temperature Monitoring and Tracking:** Temperature-monitoring technology provides end-to-end visibility of sensitive shipments, preventing temperature excursions and loss of valuable materials.
- **Build Shipping Redundancy:** Leveraging multiple shipping carriers reduces the risk of transportation failures. Because different carriers have transportation hubs in different locations, this strategy helps mitigate delays in the event of severe weather, or other operational interruptions.
- **Customized Kitting and Logistics:** Detail orientation and customization of specimen collection kits and logistics strategies ensure that sites receive pre-labeled, protocol-specific kits, reducing the risk of errors and improving operational efficiency.
- **Industry Comparison:** As documented in the PMC study by Lai et al. (2021), logistical inefficiencies remain one of the most common drivers of clinical trial delays. "...logistical issues such as shipment delays and customs clearance problems" were among the most common reasons for site activation delays.— Lai et al., 2021. Versiti's ability to pivot quickly and maintain consistent delivery timelines—even during global disruptions—demonstrates superior operational agility and risk resilience

Proven Reliability – Optimized Logistics for Cost Savings: For a global clinical trial, Versiti delivered over \$600,000 in shipping savings by optimizing routes and negotiating with carriers. Depth in carrier options, and contingencies allowed for robust cost comparisons and negotiating for building a custom logistics solution.

4. Communication and Collaboration: A Unified Approach

Clear, consistent communication is vital for de-risking clinical trials. Strategies to enhance collaboration include:

- **Dedicated Project Managers:** Each clinical trial is assigned a dedicated project manager, providing a single point of contact to streamline communication and reduce delays.
- **Collaborative Partnerships:** Versiti collaborates closely with sponsors, CROs, and sites, ensuring seamless information flow and faster issue resolution. By way of initial project kick-off meetings, regular weekly check-ins, and personalized communication and transparency, as needed.

Proven Reliability – Optimizing Project Management: By having a dedicated project manager, that effectively monitors sample and logistics efficiency, Versiti saved a sponsor the equivalent of one full-time employee's (FTE) effort.

Conclusion:

In today's high-stakes clinical trial environment, mitigating supply chain risk is not just a necessity, it's a competitive advantage. Versiti Clinical Trial Services leads the way with proven, crisis-tested strategies, deep domain expertise, and unmatched operational agility. By prioritizing reliability, responsiveness, and customization, Versiti empowers sponsors to overcome industry-wide bottlenecks and bring breakthrough therapies to patients faster and more efficiently.

1. Lai, J., Forney, L., Brinton, D. L., & Simpson, K. N. (2021). Drivers of start-up delays in global randomized clinical trials. *Therapeutic Innovation & Regulatory Science*, 55(1), 212–227. <https://doi.org/10.1007/s43441-020-00207-2>



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