EXPERIC

Clinical Trial Supply in the U.S. and Europe: What International Sponsors Need to Plan For – Part II

Cross-Border and Temperature-Controlled Logistics, Customs, and Clinical Trial Supply Management Considerations

By Matthew Mollan, Ph.D., Chief Executive Officer, Experic

Manufacturing a compliant clinical trial product for the US, EU, or UK is only half the challenge. Getting that product to trial sites while it is still within its usable shelf life, in the right condition, and with the right paperwork is a separate undertaking that trips up international sponsors just as often. Part I of this discussion addressed regulatory authorization, GMP requirements, packaging, labeling, blinding, and comparator sourcing. Part II turns to an examination of logistics after manufacturing is complete.

Cross-border logistics for clinical trial materials involve customs declarations, import/export licensing, and documentation requirements that vary by country and product type. Temperature-controlled products add another layer of complexity, as cold chain logistics must account for transit delays, customs holds, and last-mile delivery to sites with limited storage infrastructure. Add the demands of clinical trial supply management, from forecasting and depot selection to resupply planning aligned with enrollment timelines, and the margin for error narrows considerably.

Part II examines these issues in detail, along with the pitfalls that most often catch international sponsors off guard when planning trials across the US, EU, and UK.

Importation, Customs, and Cross-Border Logistics

International sponsors can import clinical trial materials into the US, EU, or UK rather than manufacturing them locally. Importation can increase supply security through manufacturing redundancy but introduces other complexities.[1] Appropriate planning and realistic timelines are essential. Customs brokers generally file the necessary paperwork with local authorities, and these services can be accessed through pharmaceutical clinical trial logistics providers.

Imported investigational medical products must still have active regulatory approval (IND or CTA), be manufactured in accordance with the region's or country's GMP requirements, meet all packaging and labeling requirements, and include all requisite customs documentation. Sponsors importing into the US must identify the Consignee in the US, which may be the qualified investigator named in the IND or a domestic agent responsible for the control and distribution of the IND.[2]

Companies importing into the EU and UK must have an EU or UK MIA and a designated EU- or UK-based QP, respectively, to confirm GMP compliance.[3] Controls must also be in place to manage the storage (in a licensed depot or distribution center) and distribution of investigational medicinal products in compliance with Good Distribution Practice (GDP) requirements. Importers to the UK must also account for a potential 20% import value-added tax (VAT) and meet strict supply-chain tracking requirements.

Cross-border logistics for clinical trial materials involve customs declarations, import/export licensing, and documentation requirements that vary by country and product type

Customs Documentation and Trial Supply Management

Clinical trial materials must be supplied in the right quantities at the right times to the right patients and labeled appropriately to support the trial format. The increasing complexity of global clinical trials and the rising interest in decentralized/hybrid designs have made this aspect of clinical trial operations more challenging, particularly for international sponsors running global trials in multiple locations.

Advanced supply management technologies have become essential for efficient supply planning, including forecasting and randomization.[4,5] Randomization and Trial Supply Management (RTSM) systems automate many aspects of clinical trial supply management, such as predicting drug demand and tracking medical kits. These systems benefit from adaptive randomization, artificial intelligence-driven forecasting, and natural language processing capabilities.

RTSM systems typically include multiple components: supply-chain management capabilities and Interactive Response Technology (IRT), which encompasses Interactive Voice Response (IVR) and Interactive Web Response (IWR) services. Together, these technologies use real-time data to enable unbiased, random assignment of patients to study groups or treatment arms; manage patient progression through trial schedules; allocate drug products to the right patients at the right locations; forecast supply; track inventory; automate resupply; and generate audit trails. These capabilities minimize risk, reduce costs and drug waste, accelerate study start-ups, and improve patient safety, trial efficiency, and regulatory compliance.

Several RTSM software platforms are available on the market, each with its own capabilities. The best platforms are configurable to allow study protocol amendments, support numerous complex trial designs, and integrate readily with electronic data capture systems used to collect study data. In addition, international sponsors should work with contract development and manufacturing organizations (CDMOs) that have experienced clinical supply managers who support real-time supply visibility.[6]

The best option is to partner with a CDMO that operates in both the home country and the target jurisdiction, has knowledge of the specific regulatory requirements for that country or region, has available capacity for immediate onboarding of new projects, has experienced clinical supply managers, and has a strong relationship with a reliable clinical trial logistics provider with cold-chain capabilities

Cold Chain and Temperature-Controlled Logistics

Most biologic drugs and biologic materials (e.g., patient samples) are unstable at room temperature and must be kept cold to prevent degradation. For some, refrigeration at 2-8 °C is sufficient, but others require freezing at -18 °C, deep-freezing at -80 °C, and, in some cases (such as for cell and gene therapies), cryogenic freezing at -150 °C using liquid nitrogen.[7] Cold chain logistics involves maintaining these products at the appropriate temperature throughout storage, packaging, and transport to ensure product quality and patient safety, avoid product losses due to temperature excursions, and achieve regulatory compliance.

Effective cold-chain logistics management ensures an unbroken cold chain. It requires extensive scientific knowledge; an understanding of the appropriate use of advanced temperature-controlled packaging, shipping, and information technologies; and logistics planning capabilities.[8] Comprehensive cold-chain logistics

solutions for clinical trials encompass specialized infrastructure, equipment, and procedures, all designed to maintain drug product or sample integrity from production or collection through delivery to the final destination.[9] Specific components include cooling systems, specialty packaging materials, and advanced monitoring capabilities that use electronic sensors and data loggers for real-time condition tracking.

International sponsors planning to run clinical trials in the US or EU for temperature-sensitive drug products must have a cold-chain management strategy. The optimal approach is to partner with a CDMO that has an established relationship with a reliable cold-chain logistics service provider.

Common Pitfalls for International Sponsors Planning Clinical Trials in the US/EU/UK

International sponsors conducting clinical trials in the US, EU, and UK face several challenges that lead to common, potentially costly mistakes.[10,11] Many of these difficulties stem from differences in regulatory expectations across these three regions/countries and from the regulatory requirements in their home jurisdictions. Some of the greatest issues arise during trial set-up, but many also relate to improper packaging and labeling of clinical trial materials and to poor clinical trial logistics planning and management, particularly for temperature-sensitive products and materials.

Achieving Success with a Single CDMO Partner

Clinical trial materials for studies in the US, EU, and UK can be produced by the sponsor or a CDMO partner in the home country, by the sponsor in an owned facility in the target country/region, or by a local CDMO partner. For international sponsors, the first route is the most challenging option, particularly for companies in developing nations. Building a facility in the US, EU, or UK is very expensive and extends program timelines. Talent shortages add further complications.

The best option, therefore, is to partner with a CDMO that operates in both the home country and the target jurisdiction, has knowledge of the specific regulatory requirements for that country or region, has available capacity for immediate onboarding of new projects, has experienced clinical supply managers, and has a strong relationship with a reliable clinical trial logistics provider with cold-chain capabilities.

A single US CDMO partner that can develop and manufacture drug substance and drug product, supported by in-house testing, as well as package and distribute products, dramatically simplifies and streamlines clinical trial material supply, saving time and cost while reducing risk. These benefits are magnified when one project manager serves as the key point of contact, providing an effective communication channel and helping build strong relationships. Optimal CDMO partners also have effective solutions for managing time zone challenges, language barriers, and cultural differences. Here again, a CDMO that operates in multiple regions offers many advantages.

REFERENCES

1. Dan Pritchard, "Import/export and Clinical Trial supply," https://midwinter-solutions.com/import-export-and-clinical-trial-supply

2. FDA, "Importing Investigational New Drugs," June 15, 2026. https://www.fda.gov/drugs/human-drug-imports/importing-investigational-new-drugs

3. Jgao, "Investigational Medicinal Product (IMP) Importation into the EU: 3 Key Considerations for Success," HiTechHealth, Apr 7, 2026. https://hitech-health.com/imp-importation-eu-clinical-trials/

4. "RTSM Software Comparison: Trial Supply Management Guide," April 5, 2026. https://intuitionlabs.ai/articles/rtsm-software-comparison-trial-supply

5. Ian Davison and Marc Weinberg, "RTSM in Clinical Trials: A Guide to Randomization and Trial Supply Management," Medrio Blog, September 5, 2024. https://medrio.com/blog/what-is-rtsm/

6. Ed Groleau and Henk Dieteren, "The cornerstone of clinical trial success: selecting seasoned CDMOs and IRT vendors," International Clinical Trials, Summer 2024. https://www.suvoda.com/hubfs/ICT%20Summer%202024%20CTS%2BL%20Supplement%20PCI%20and%20Suvoda.pdf

7. World Courier, "What is cold chain logistics? A complete guide," June 3, 2026. https://www.worldcourier.com/insights/what-is-cold-chain-logistics---a-complete-guide

8. Jean-Paul Rodrigue and Theo Notteboom, "The Cold Chain and its Logistics," Transport Geography, https://transportgeography.org/?page_id=6585.

9. XPO Logistics, "What is Cold Chain Logistics?" Oct. 9, 2025. https://europe.xpo.com/en/resource-center/what-is-cold-chain-logistics/

10. Mark Swanson and Steve Gompertz, "From MHRA/EMA to FDA: Navigating the Clinical Data Divide for US Market Access," April 29, 2024. https://gotomarket.global/content/navigating-clinical-data-divide-europe-to-usa/

11. Leher Gumber et al., "Operational complexities in international clinical trials: a systematic review of challenges and proposed solutions," BMJ Open 14(4):e077132 (2024). doi: 10.1136/bmjopen-2023-077132

ABOUT THE AUTHOR



Matthew Mollan, Ph.D.
Chief Executive Officer, Experic

Matthew Mollan, Ph.D., brings more than 30 years of leadership experience across pharmaceutical development, manufacturing, and clinical supply. A strategically focused operations executive, he is known for driving growth, operational excellence, and high-performing teams.

Prior to Experic, Matthew served as Vice President of Operations, Early Phase, at Catalent, where he led a multi-site U.S. and UK network supporting Phase I–III programs. He expanded capabilities, strengthened quality systems, and advanced key growth initiatives. Earlier, he led Catalent's Drug Delivery Solutions business in Kansas City, transforming it into a core strategic site with expanded capacity, enhanced technologies, and a strong reputation for scientific rigor.

Matthew has also held leadership roles at Aptuit, Pfizer, Warner-Lambert/Parke-Davis, and Carter-Wallace, building deep expertise in drug product development and novel dosage forms. He holds a Ph.D. in Pharmaceutical Science and a B.S. in Pharmacy from Rutgers University.