Clinical trials

Beyond the warehouse

How regional logistics strategy supports clinical success in Europe

Introduction

Regionalization reshaping the path to market

In recent years, the pharmaceutical industry has been undergoing a quiet transformation. A combination of geopolitical pressures, shifting trade policies, and the rising cost of trial execution in traditional markets has driven many sponsors to rethink their market-entry strategy. An emerging trend is a growing emphasis on Europe as a key region for clinical development.

While the United States continues to play a critical role in advancing early-stage research and innovation, many organizations are also recognizing the strategic advantages of expanding development and launch activities within Europe. Factors such as a strong regulatory framework, coordinated regional initiatives, and recent efforts under the EU Strategic Agenda 2024–2029 to enhance clinical trial competitiveness are helping to make Europe an increasingly attractive environment for clinical research.

In this environment, logistics has shifted from being an operational afterthought to a strategic necessity. Decisions made early about where and how to position infrastructure can determine whether a program navigates the EU landscape efficiently or becomes mired in regulatory and operational delays. For advanced therapies like cell and gene treatments (CGTx), logistical missteps can even compromise product viability.

Regional logistics strategy

New expectations, new complexity

The EU Strategic Agenda calls for bolstering research competitiveness, strengthening supply chain resilience, and deepening regulatory alignment within and beyond Europe. The vision is compelling, but the operational reality is more complicated.

Sponsors must navigate regulatory fragmentation across member states, manage differences between European Medicines Agency (EMA) and US Food and Drug Administration (FDA) requirements, and plan for longer start-up timelines due to country-specific ethics and regulatory reviews. For CGTx programs, where product stability windows can be measured in hours or days, every additional step in the supply chain carries risk.

In response to these hurdles, there has been a shift toward regional clinical execution and strategic localization. Instead of simply importing a US or global process into Europe, sponsors are designing their logistics models for EU conditions from the start. That means investing in regional hubs, integrating packaging and labelling capabilities closer to trial sites, and building redundancy into critical cold chain flows.

Planning for success

Infrastructure and integration from day one

Early-stage planning is where logistics can make or break a clinical trial. This goes beyond utilizing a local storage facility; infrastructure must align with regulatory requirements, minimize customs exposure, and enable rapid responsiveness to unpredictable trial dynamics.

Cold chain alignment is a particularly critical factor. For CGTx products, which often require ultralow or cryogenic storage, even brief temperature excursions can render a batch unusable. This necessitates robust equipment and carefully choreographed handoffs between manufacturing, storage, and delivery.

The experience of one biotech offers an example of how early infrastructure design supports the success of a product. The company required a highly reliable just-in-time (JIT) packaging, labelling, and distribution process for a clinical solution therapy across both UK and EU sites. With delivery timelines of just 5 working days for the UK and 8 days for the EU, any misalignment in planning could have delayed treatments.

By establishing a two-facility workflow consisting of packaging and initial Qualified Person (QP) release in Bishop's Stortford (UK), followed by a stop in Hegenheimer (Germany) for EU QP release, they were able to meet strict timelines while navigating complex multi-country compliance. This early integration of regulatory and cold chain strategy ensured on-time delivery with no treatment delays.

Cold chain demands for CGTx

Where location meets viability

Cell and gene therapies have transformed treatment possibilities, but their logistical requirements make them uniquely challenging to deliver. Autologous therapies, where a patient's own cells are modified and returned, require cryogenic storage and tightly controlled transport timelines. Any delay, be it from customs, weather, or equipment failure, can compromise product integrity and, by extension, patient outcomes.

Co-locating trial and manufacturing infrastructure can mitigate these risks. By shortening the physical and regulatory distance between production and administration, sponsors can reduce handoffs, avoid customs delays, and enable JIT supply directly to treatment sites.

This principle is reflected in a large biopharma's Germany hub initiative. The company, already operating commercial autologous products, recognized the need for redundancy in its EU operations in order to protect supply continuity and to manage clinical trials alongside commercial shipments. Partnering with a provider capable of 7-day operations, the large biopharma gained the flexibility to ship on weekends, a critical advantage for time-sensitive therapies.

The facility's capacity for cryogenic and –80°C handling, combined with its ability to operate outside standard business hours, reduced the risk of missed treatment windows. Thanks to this technical capability and operational flexibility, the large biopharma was able to complete over 100 shipments on time in the first few months.

Quiet infrastructure, big impact

Why regional logistics matter more than ever

For many sponsors, infrastructure is most visible when something goes wrong, whether it be a delayed shipment, an incorrect label, or a cold chain excursion invalidating an entire batch. The value of a regional strategy lies in building a strong foundation so that these issues never occur in the first place.

Regional hubs reduce the number of handoffs between carriers and storage locations, mitigating the risk of temperature excursions or documentation errors. They allow for localized delivery schedules that can be tailored to patient appointments, and the agility to respond to unexpected changes in manufacturing or clinical schedules.

The large biopharma's Bleiswijk hub in the Netherlands illustrates this principle in action. Designed as an autologous distribution hub, the site adapted its processes to the sponsor's scheduling and quality protocols from day one. Integration with customer systems enabled rapid scheduling and communication, while client-specific documentation and staff training safeguarded product safety and chain of identity.

Within the first 4 months, process improvements reduced receipt turnaround time from 1.6 days to just 0.6 days, enabling faster QP release and onward delivery. Every dispatch shipped on the scheduled day, and no quality-impacting events were recorded. This level of quiet reliability is the hallmark of effective regional infrastructure, allowing trials to progress and commercial supply to flow without disruption.

Conclusion

Clinical confidence starts with regional foresight

Prioritizing regional logistics isn't just about meeting regulatory requirements or capitalizing on market opportunities, it's about building confidence. Sponsors need to know that when a therapy is ready, the infrastructure is already in place to move it quickly, compliantly, and safely to patients.

As the case studies of the biotech and biopharma demonstrate, this confidence doesn't happen by accident. It's the result of deliberate choices made early: to invest in regional hubs, to integrate regulatory checkpoints into supply flows, and to design cold chain strategies specifically for CGTx products.

In an era where trial delays, customs bottlenecks, and fragmented regulations can derail even the most promising program, logistics has become a strategic asset. For sponsors aiming to make Europe a priority on the path to market, the message is clear: success starts well before the warehouse. It starts with the foresight to build regional capabilities that can flex with the demands of both today's trials and tomorrow's commercial launches.

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