Thermo Fisher SCIENTIFIC

GLOBAL CLINICAL SUPPLY SOLUTIONS FOR EVERY TRIAL

DELIVERING THE RIGHT DRUG TO THE RIGHT PATIENT, ON-TIME, IN-FULL, AND WITHOUT COMPROMISE

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HOW SPRING BREAK HAD TO WAIT A LITTLE LONGER, SO A BABY COULD HAVE A BETTER SHOT.

After a long night of packing for her family's spring break vacation, Holli woke up at 4:40 AM Saturday morning. She noticed a text message on her phone. A six-day-old baby experiencing violent seizures needed a client's medication immediately. Vacation was going to have to wait. By 5:20 AM, Holli was on the phone with the client to identify a solution. By 7:30 AM, she and her team were at the site (normally closed on Saturdays). The client had received an emergency Treatment IND from the FDA the night before. Next, through Thermo Fisher's Total Transportation Management capability, they were able to arrange same-day shipment from their TSA-certified warehouse. No red tape. No delay. No package opening at the airport. The package went directly on a commercial flight, and was hand delivered to the hospital 12 hours after Holli received that text. Best of all, when every moment mattered most, a baby in urgent need could be treated with the client's medication in hours instead of days.

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At the center of every clinical trial is a patient waiting for a treatment to arrive safely and on-time.

In the highly competitive, new drug development market, biopharma companies face a myriad of challenges—from balancing cost, time, and quality, to delivering the best possible outcome for their trial and their patients. As biopharma companies move toward an Investigational New Drug (IND) application and their first human trial, many of them find themselves lacking the experience and knowledge in securing a reliable clinical supply chain strategy. A reliable clinical supply chain strategy is as essential as a company's discovery program—making finding a partner who can help guide a comprehensive supply chain strategy and manage day-to-day supply chain activities, paramount.

Building a clinical supply chain strategy as reliable as your discovery program

Clinical trial supply chains can be complicated, and one small oversight can significantly slow things down.

Delivering drugs to patients is the top priority and is a significant milestone as biopharma companies complete their drug development. A trial cannot begin unless patients are registered, and both the investigational drug and ancillary components are in place.

While building a clinical supply chain strategy, ask yourself:

- How do I build my packaging strategy?
- What about labels?
- What if the drug requires temperature-controlled storage and special handling?
- When should I plan for ancillaries?
- How do I plan for comparator sourcing?
- Where can I find information about import and export regulations?
- How should I design my clinical trial to recruit and retain patients?
- Can I outsource my clinical supply chain to one vendor? Or will I need to outsource each piece to a different vendor?

Unfortunately, many biopharma companies may not have the required capabilities to meet these challenges and find themselves in need of a partner who can deliver their clinical trial needs regardless of size, phase, therapeutic area, country, or region.

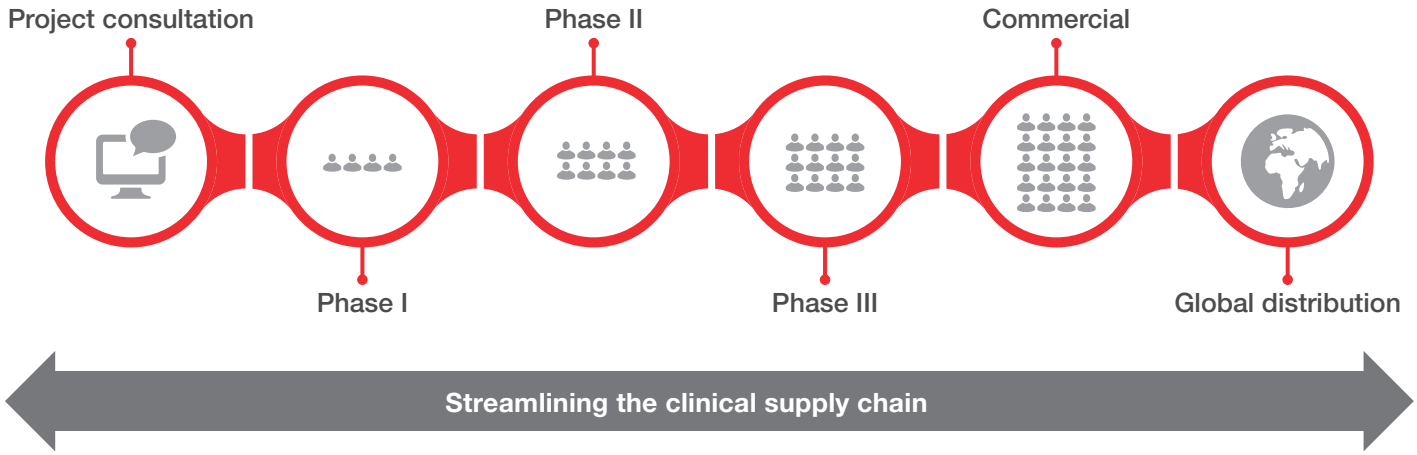
Components of a successful clinical supply chain strategy

Keep your trial running smoothly with early planning and oversight across the entire process.

Upfront planning has become a critical component to executing a streamlined, efficient, and nimble clinical supply chain. As such, clinical supply partners play a more active role in overseeing and managing the strategy—this includes forecasting, comparator sourcing, ancillary sourcing, packaging, labeling, distribution, and logistics.

A successful clinical supply chain strategy should address the following components:

Covering all phases of development



- Study planning and setup
- Regulatory compliance insights
- End-to-end supply chain and inventory management
- IRT integration
- Label design and translation management

- Over-encapsulation, blinding
- Blister packaging, carding, vials, syringes, auto injectors
- Comparator & ancillary material sourcing
- Global biobanking
- Laboratory services

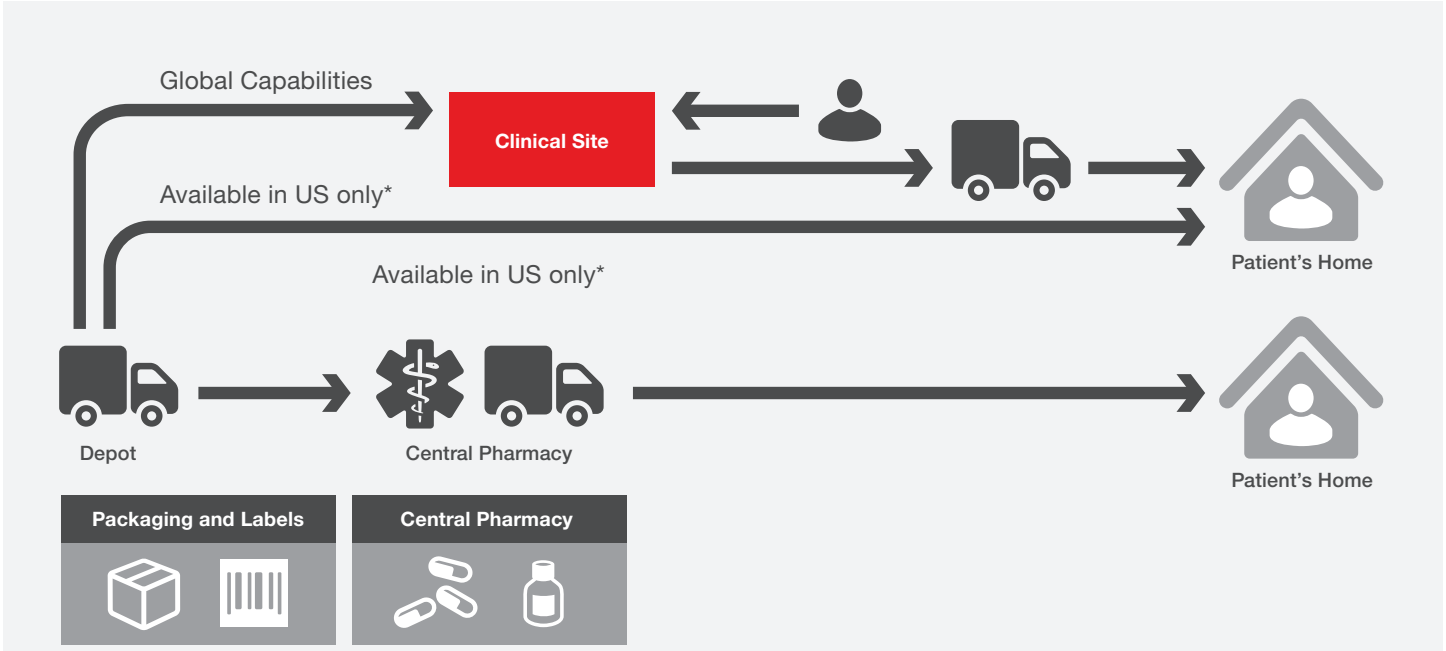
- Commercial packaging
- Global distribution, with real-time visibility via Global Gateway
- Cold chain network for time and temperature sensitive material
- Global customs and regulatory guidance

- **Clinical trial packaging** strategies are often impacted by changes to the protocol such as dosage changes, increases or decreases in volumes, changes to expiry dates, and inclusion/exclusion of countries that weren't part of the original plan.

- Every study requires a **label** strategy as labels are needed for every product, comparator, and shipping box. Furthermore, unlike other medicinal products, every clinical label design is unique to every patient.

- **Packaging and storage** plans need to ensure the quality of the study's medicinal products and placebos meet the needs for temperature, humidity, lighting, and other environmental controls.
- **Cold chain management** is critical for products and samples that need to be packaged, picked, and packed for distribution and stored within specific regulated temperatures. These highly controlled areas must follow strict quality standards before being released for treatment.
- Sourcing **clinical trial ancillary supplies** is much more than just procurement. It requires an understanding of the study's design and requirements, in-depth knowledge of international regulations, and rigorous, proactive planning to ensure the most appropriate equipment and materials are purchased. All while acquiring at the right time and at a competitive price.
- With patient pools expanding to remote locations across the globe, managing the **transportation** of life science shipments has become increasingly complex. The growth of biologics creates additional challenges due to cold chain handling, storage, and distribution requirements.
- The traditional clinical trial model isn't always convenient for the patient due to their location, schedule, or lifestyle, which leads to under enrolling or high dropout rates. **Decentralized clinical trials** enable patients to participate in clinical trials from their homes by providing them with study drugs and care where they live.

Direct-to-patient options at a glance



Direct-to-patient solutions accelerate recruitment, providing patients with more convenience and reducing dropout rates

CASE STUDY

Meeting milestones and patient needs through expedited delivery of Phase I materials.

SUMMARY: Reneo Pharmaceuticals, a clinical-stage pharmaceutical company, focuses on the development of therapies for patients suffering from genetic mitochondrial disease. The pressure of delivering safe and effective drugs to patients, in a timely manner, is critical—as the quality of patient lives depends on it.

CHALLENGE: Reneo needed a way to expedite early testing in order to make informed proof of concept decisions and complete their regulatory submissions. They were looking for a partner that could provide both product development and clinical packaging services.

SOLUTION: Reneo took advantage of Thermo Fisher Scientific's **Quick to Clinic**™ program for Oral Solid Dose. This program delivers an oral solid dose product along with labeling and packaging for Phase I clinical trial in as little as 14 weeks from API supply, including one-month stability data.

IMPACT: By developing phase-appropriate formulations for oral solid dose forms, Reneo was able to save both time and money because the speed at which they were able to get to clinic, allowed them to generate a proof of concept a lot quicker. In addition, Reneo was able to eliminate multiple quality agreements and master service agreements by working with Thermo Fisher Scientific under a single contract.

"Working with a CDMO is more about a partnership than a customer-supplier relationship. And I feel that's what we have between Reneo and Thermo Fisher Scientific."

— Helen Barker, Senior Director, Head of Pharmaceutical Development at Reneo Pharmaceuticals

Streamlining delivery through a single vendor

From Phase I to Phase III, domestically or globally, you need a partner to collaborate with you at every step of the way to serve the ultimate beneficiary—the patient.

Thermo Fisher Scientific prides itself on making your therapies, timelines, and patients as much of a priority as you do. Whether you need primary or secondary packaging of your clinical drug for storage, distribution, logistics, labeling, comparator sourcing, ancillary sourcing, and clinical supply chain management through to returns, our global team can meet the needs of every trial. Regardless of size, phase, or therapeutic area, our attention to quality, global capacity, and depth of expertise will help provide a better clinical trial experience. As a partner who specializes in clinical supply chain management, we can demonstrate a history of successful collaboration, knowledge of industry best practices, a track record of innovation, and a solution that adds value.

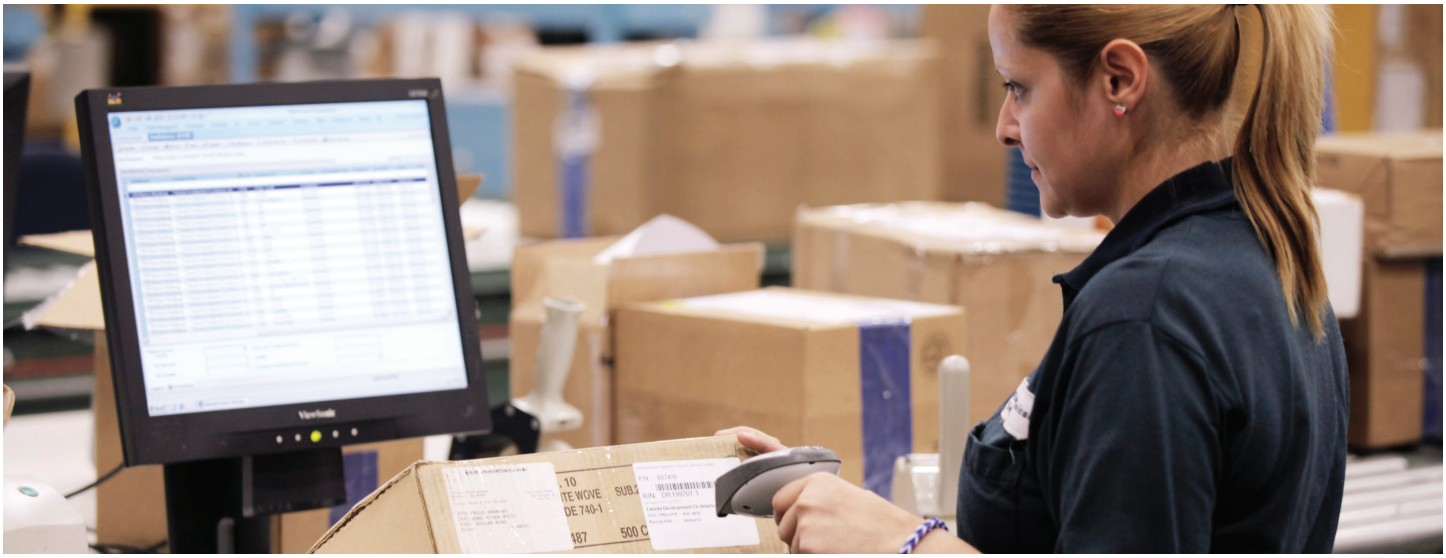
With more than 55 locations globally, we provide our clients with integrated, end-to-end capabilities through all development phases—including API, biologics, viral vector services, cGMP plasmids, formulation, clinical trial solutions, logistics services, and commercial manufacturing. Our 29 purpose-built GMP/GDP compliant facilities, supported by over 38 partner depots—located across five continents—provide the global presence, information systems, and quality standards giving clients the flexibility, access, and assurance needed for clinical trials.

>15 million
samples in freezers & LN2 tanks

31M+
labels printed in 2019

~413,000
clinical shipments completed in 2019

6,000+
clinical trial projects supported in 2019



Global footprint, local expertise, breadth of service offering

Distribution

- Total Transportation Management
- Regional hubs to increase flexibility & mitigate risk
- Importer-of-record capability in 20+ countries

- Local inventory management and packaging services
- Real-time visibility to inventory & distribution data

- ~400,000 clinical supply shipments annually
- 2 million samples shipped and received annually
- Cold chain material management

- 3,500+ employees
- Project management expertise w/single point of contact
- Global logistics help desk

Global footprint

- 29 purpose-built cGMP facilities
- 80+ primary packaging rooms
- 135+ secondary packaging rooms
- Qualified Person (QP) release
- Local subject matter expertise

Strategically located in emerging regions

Integrated global IT systems & quality networks

With our global reach and local care, we can meet your unique requirements, no matter where in the world you're conducting your trial. Contact us to learn how we can help with your next clinical trial.

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