



# CLINICAL TRIAL SUPPLY SOLUTIONS

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

**Holli Carlson**  
*Client Services Director,*  
*Pharma Services*  
Mt. Prospect, IL



## **The drug development landscape has changed. Our commitment to best-in-class clinical trial solutions has not.**

Nowhere is this more evident than in clinical supply management. Companies are recognizing the strategic importance of clinical supplies in ensuring drug development risks and costs are well understood and anticipated for in advance. Upfront planning has become a critical component to executing a streamlined, efficient and nimble clinical supply chain. As such, clinical supply professionals are playing a more active role in development and study planning, managing mission critical activities, forecasting and mitigating operational risk.

For over 30 years the Thermo Fisher Scientific team has been committed to helping sponsors of all sizes develop comprehensive clinical supply plans that incorporate the need for flexibility in trial execution with a balanced risk and cost approach. From complete clinical supply plans, to comparator sourcing strategies, distribution strategies and packaging design recommendations, our experts are on hand to meet any of your strategic planning requirements.



## Robust Fisher Clinical Services<sup>SM</sup> supply chain solutions to meet your clinical trial needs.

### PACKAGING DESIGN & PRODUCTION

Keeping the patient in mind is key to identifying the most optimal packaging configuration for your trial. Our team of project managers in combination with our packaging engineers can assist you in identifying the most suitable packaging for your clinical trial in order to ensure patient safety and compliance.

**Services include:** Primary, Secondary, Overencapsulation, Pre-filled syringe, Tamper-evident, Blinding, Climate-controlled (including Cold Rooms)

### LABEL SERVICES

Whether needing to implement an Approved Phrase Library (which has been shown to shorten label cycle times by more than 50 percent) or determining the appropriate label type, text and strategies for your trial, our experienced and dedicated label project management teams can help you build the strategy that will deliver results both long and short term.

**Services include:** Booklet, Single & Multi Panel, Digital, Alternative Translation & Label Approval System (ATLAS<sup>SM</sup>)

### BIOSERVICES

Ensuring a seamless workflow which connects the sponsor, bio-manufacturer, clinical center, and patient into a well-coordinated chain of custody is our specialty. As the leader in managing critical biological material, we provide our customers with customized solutions to store, package, and transport their valuable material.

**Services include:** Biobanking & Biorepository, Laboratory Processing, Qualification / Validation, Kit Production, Cold Chain Logistics

## GLOBAL DISTRIBUTION

Given the ever-expanding global nature of today's clinical trials, sponsors demand and deserve the assurance that their needs will be met regardless of location, and in accordance with a consistent global quality standard. Our 20 purpose-built GMP/GDP compliant facilities, supported by over 30 partner depots—located across five continents—provide the global presence, information systems and quality standards to provide clients the flexibility, access and assurance needed for their clinical trial.

**Services include:** Ambient, Refrigerated & Cold Storage, Controlled Substance Storage, GDP Distribution Services to over 150 countries

## TOTAL TRANSPORTATION MANAGEMENT

Managing the transportation of life science shipments has become increasingly complex over the years, with patient pools expanding, often to remote locations across the globe. In addition, the growth of biologics creates additional supply chain challenges due to cold chain handling, storage and distribution requirements.

Our logistics specialists and teams of in-country experts can simplify the complexity associated with transportation planning and monitoring and, as a result, optimize transportation performance and costs across the supply chain.

**Services include:** Supplier Qualification, Mode Optimization, Courier Selection & Management, Customs & Regulatory Guidance, Importer of Record, Cold Chain Supplies Management, Dispatch Services, Proactive Track & Trace, Data-Objective Monitoring & Reporting, and Consolidated Billing

## COMMERCIAL DRUG SOURCING

Sourcing comparator, rescue medication, or comedication for clinical trials is not merely a purchasing or procurement exercise. Applying a strategic approach, evaluating every sourcing factor and creating a customized plan with multiple options results in an optimal comparator sourcing strategy.

**Services include:** Comparator, Comedication, Rescue medication sourcing

## CLINICAL SUPPLY OPTIMIZATION

Leveraging the expertise of a dedicated supply chain team, proprietary technology tools and an extensive cGMP network, we provide proactive guidance in the development of supply strategies, as well as overarching simulation, forecasting and cost management. This team of professionals can assist you in identifying the most optimal packaging configuration, establishing & verifying IRT setup, forecasting patient clinical supply requirements by country and identifying the regulatory hurdles you will face based upon your current country selection.

**Services include:** Forecasting, End-to-End Supply Chain Management, Centralized Project Management, Consolidated Reporting

## CLINICAL ANCILLARY MANAGEMENT

It's easy to forget about ancillaries when immersed in the details of a global clinical supply chain. Our dedicated team of clinical ancillary project managers can help you develop a complete ancillary strategy that will ensure your sites are appropriately stocked at time of First Patient In and in accordance with regulatory requirements.

**Services include:** Sourcing, Inventory Management, Distribution, Ancillary Returns Management

## QP SERVICES

For strategic planning purposes, our team of QP's are available to provide advice on your expiry strategy, including the most current conditions required by regulatory authorities.

**Services include:** Regulatory Oversight, Compliance Guidance

**Chris, Lauryn,  
Carson Rose  
& AJ Tubesing**



# MADE FOR

## HOPE & FAMILY

### HOW A FAMILY'S PERSEVERANCE HELPED THEM REACH A SEEMINGLY UNATTAINABLE GOAL.

As members of the United States Air Force, Lauryn and Chris were as healthy and fit as a young couple could be. But when two of their three children tested positive for Cystic Fibrosis, everything changed. Along with endless treatments, trips to the doctor, and fear of catching even the slightest cold, was the realization that a typical life expectancy was of only about 31. They soon learned of a “wonder drug” that was helping CF patients in trials, and actually treated the disease, not just the symptoms. When they were finally approved, it took only 6 months for their doctor to say something they hadn't heard before: “Your daughter looks healthy.” Now, with a life expectancy into the 60s and beyond, these two veterans are free to have all the dreams parents have for their kids.



+1 610-391-0800 • [pharmaservices@thermofisher.com](mailto:pharmaservices@thermofisher.com) • [www.fisherclinicalservices.com](http://www.fisherclinicalservices.com)

© 2020 Thermo Fisher Scientific Inc. All rights reserved.  
Published 2/20 PSG0757

**ThermoFisher**  
SCIENTIFIC