ThermoFisher SCIENTIFIC

MADE WITH

ACCURACY & ACTION

WHITEPAPER

Considerations for your first clinical trial

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

patheon

Abstract

After years of research and multiple rounds of funding, you are finally ready for the first phase of clinical trials. The competition is fierce and time is of the essence. Given the number of drugs that don't survive all phases of development, the odds are against you, but you are determined to succeed. And while you know everything there is about your Investigational Medicinal Product (IMP), you realize that it's only one small piece of running a successful clinical trial.

Read this whitepaper to learn why sponsors should consider partnering with an organization with demonstrated expertise, ability to work across geographies and cultures, a keen understanding of local and international requirements, and that offer models for support at multiple levels.

Introduction

For a small and emerging biopharma, moving into the clinical trial phase of development can be overwhelming. In-house resources tend to be focused on the science or on generating funds. The limited administrative resources serve in multiple roles where they do many things well but aren't necessarily experts in the areas essential to running a clinical trial. Engaging a consultant and/or a Clinical Research Organization (CRO) is often a first step. Their expertise can help with designing a trial, defining strategies for patient enrollment, and implementing technology solutions to track progress.

Although helpful, it is important to understand that CROs do not typically manage the comprehensive clinical trial supply chain. What are the gaps? The new therapy needs to be packaged and labeled. There are supporting materials such as related consumables and possibly instruments or equipment that need to be procured for investigative sites. These ancillary materials and the IMP often require storage in regional hubs. Logistics expertise is required to ensure everything appears on time, in full and at temperature.

Managing the many moving parts of a supply chain is one of the most time-consuming and intricate of all the factors involved in the clinical process.

Experienced clinical supply providers, such as Thermo Fisher Scientific, have exposure to small local and large multinational trials and thousands of protocols every year across numerous therapeutic areas. As a result, these providers develop industry best practices that can be leveraged in support of a clinical trial. This paper reviews seven 'best practices' to help ensure a successful trial.

Clinical trial supply best practices

1. Develop clinical logistical support

Develop a comprehensive logistical supply plan. Managing the many moving parts of a supply chain is one of the most time-consuming and intricate of all the factors involved in the clinical process. Logistical support involves engaging strategically placed facilities and depots around the globe.

This ensures that the supply chain solution addresses both the regional and country level requirements of a clinical program.

The logistics supply plan must address several key areas:

- Complying with Good Distribution Practice (GDP) during the movement of product to ensure material integrity is uncompromised
- Resources to manage, track, and transport all types of products, including temperature-sensitive compounds
- Technology to track and monitor location and temperature of in-transit goods
- Regulatory expertise to ensure timely customs clearance, eliminating risk of temperature excursions due to import delays
- Recommendation of best mode/courier for a given origin/destination point based on objective, data-driven performance analysis across a broad range of suppliers
- Access to strategically located GMP distribution centers that can receive, store and distribute materials to investigator sites with a zero-temperature excursion mindset
- In-country experts that can work with individual clinical sites to ensure staff understand special handling requirements

2. Start early and coordinate across functions

A fair amount of savings—time and money—can be achieved to streamline the clinical supply chain if both the project management plan and the supply chain plan are done in collaboration.

This approach allows for engineering automated solutions and can consolidate non-sequential steps to speed progress and reduce risk throughout development. By creating a coordinated plan, any number of questions can be addressed before they arise, such as:

- Which countries to choose based on not only patient recruitment but the likelihood of timely delivery to sites
- The impact import and export regulations could have on trial and project timelines
- How to address re-supply and returns
- Minimizing the administrative burden on the investigator sites allows them to focus on the clinical concerns of the trials

3. Understand the regulatory environment

Today's clinical trial teams must have the requisite regulatory knowledge to develop and register new products. Without this knowledge, clinical trial applications may be delayed and/or rejected. Once the trial is in process, import/export paperwork may be incorrect or incomplete which can, in some cases, jeopardize in-transit product that is under strict temperature control.

Clinical trials are increasingly being conducted across an ever-expanding landscape of countries and regions. Perhaps the single most important factor enabling globalization is the substantial progress to date in the harmonization of regulatory strategies.

Since its formation in 1990 by regulatory authorities and research-based industry representatives of Europe, Japan and the United States, the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use—ICH for short—has improved the way drugs and vaccines are developed and registered by eliminating redundancy.

Nearly three decades later, pharmaceutical companies can do what was not possible then—demonstrate the quality, safety and efficacy of a new drug or vaccine using a single set of clinical studies, provide these data to regulatory agencies in a common format and importantly, do so electronically.

This standardization allows us the ability to design and deploy a global clinical trial in a much more effective way than has happened in the past. Where the required expertise is not available in-house, it is important to note that a clinical supply chain service provider can support sponsors in ICH countries as well as those that do not benefit from these regulations.

This standardization allows us the ability to design and deploy a global clinical trial in a much more effective way than has happened in the past.

4. Reduce waste and risk

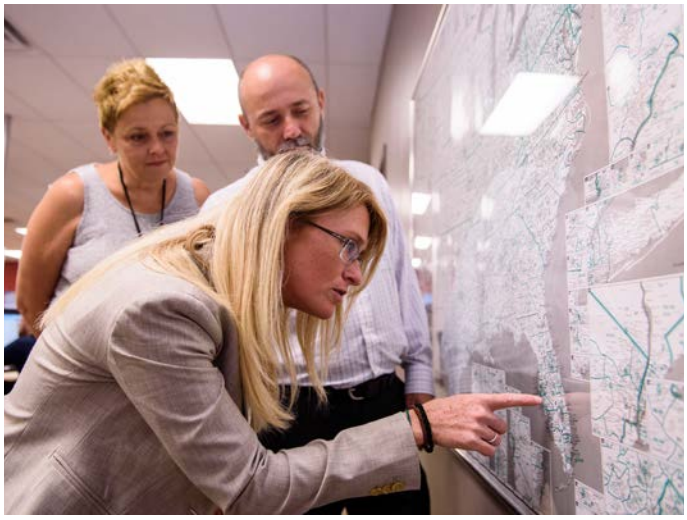
According to Thermo Fisher Scientific estimates, there is upward of 200% waste in the supply chain. Sponsors typically have a 20-week timeline from final protocol to putting clinical trial supplies in the field. Those supplies can range from the investigative drug to a series of equipment and other ancillary products required by the protocol. Supplies can range from an ECG machine to home tests for patients, to even food supplements.

A well-designed clinical supply plan will consider all inbound supplies to an investigative site, optimize the shipping and streamline what is sent to the site. This holistic approach can yield unexpected and sometimes substantial benefits for everyone.

5. Develop a flexible structure

A smaller or mid-sized pharmaceutical company has limited resources. Engaging a third party can dramatically expand their capabilities allowing the sponsor to focus on their key strengths. A clinical supply chain partner can help manage communication between the trial sponsor study team, their Contracted Drug Manufacturing Organization (CDMO), Clinical Research Organization (CRO) and investigator sites. They can also work across geographies to manage the internal and external communications and planning.

To achieve optimal results, there must be trust and open communications between the sponsor and outsourcing partner. The most successful models are ones where the sponsor has partnered with a provider that can help them access all challenging geographies, rather than a select region only. Sponsors who trust their partners by sharing plans in advance can gain the benefit of these providers investing for them in regions or technology.



6. Establish a global team

A clinical trial supply expert brings more than simply the resources to establish a global team. He or she also bring a deep understanding of the various cultures, and have experience in creating a shared sense of mission and goals within the clinical supply chain and with their clinical partners.

Identifying the right partner means more than years of experience or training. It requires ensuring that these teams work well with others, understand a multi-cultural environment, operate well under pressure, and adjust for unexpected challenges. This uniting concept translates across borders, regions, countries, languages, and cultures.

7. Think globally, act locally

A global outsourcing partner can help sponsors to consider the local challenges involved with the clinical supply chain, and they will develop a proactive plan for addressing and managing those risks. In the near-term, offshore investment has focused on many of the secondary emerging economies, such as the BRIC (Brazil, Russia, India, and China) nations, to contract preclinical and clinical research.

In the longer term, the tertiary, third-tier economies will emerge to capitalize on specific skill sets and take advantage of the cost differentials and/or infrastructure benefits to attract additional offshore investment. A supply chain partner with local expertise and presence will become an invaluable asset.

In today's challenging financial and global environment, with higher cost investigational drugs, one of the most critical considerations for clinical development is how to minimize risks in the supply chain. A set of tasks that were historically seen as in-house activities by pharmaceutical organizations are increasingly being outsourced to organizations with more capacity, a broader footprint and available resources to help them with the growing complexity of clinical programs and the expanding network of clinical sites.

It is critical for clinical and clinical supply teams to initiate collaboration early to proactively plan for any potential challenges that would delay shipping drug to sites when it is needed. Sponsors should consider partnering with an organization with demonstrated expertise, ability to work across geographies and cultures, a keen understanding of local and international requirements, and that offer models for support at multiple levels.

About us

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. We give pharma and biotech companies of all sizes instant access to a global network of facilities and technical experts across the Americas, Europe, Asia and Australia. Our global leadership is built on a reputation for scientific and technical excellence. We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. As a leading pharma services provider, we deliver unrivaled quality, reliability and compliance. Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

+1 919 226 3200 • thermofisher.com/patheon • pharmaservices@thermofisher.com

Published 08/21

ThermoFisher SCIENTIFIC