ThermoFisher SCIENTIFIC

Who's Watching Your Supply Chain?

STRATEGIES FOR MITIGATING RISK IN CLINICAL TRIALS

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

patheon

Introduction

Congratulations on finding a molecule worthy of an Investigational New Drug designation and making it to clinical trials! Now ask yourself: is your clinical supply chain ready to deliver the goods? With the ever-increasing costs of clinical trials and the advantages of being first-to-market, it's time to take a closer look at your supply chain to ensure it delivers with speed, efficiency, and quality — all within your budget. Unfortunately, many new and emerging biopharmas may not have the required capabilities in-house to meet the challenges. This whitepaper will help guide you through the numerous considerations necessary for you to decide whether to build your capability, outsource it, or create a hybrid in-source/out-source model.

The hidden dangers of a fragmented oversight model

In clinical trials, everything is interdependent--from manufacturing, packaging, labeling, and distribution, to comparators, dosing, and data gathering. This makes proper oversight and information critical to avoiding cascade failures throughout your timeline.

Frequently, companies will pursue a best-of-breed strategy in recruiting supply chain partners, opting for specialists in each of the tasks mentioned above. But rather than reducing risk, this approach can increase it. Absent extremely vigilant oversight from an overarching program manager, it allows for the very real possibility of misunderstandings about who is responsible for what. In pharma, the sheer cost of clinical trials — and potential impact on lives — raises the stakes immeasurably.

> **"People like to say, 'Well, I've done the math. I've got a hundred patients. Each patient is taking 10 doses, which means I need a thousand units. We're done, right?' Wrong."**
>
> - **Deb Knoll**
> ***Director of Clinical Specialization Services, Thermo Fisher Scientific***

Fragmented oversight can also lead to short-term thinking. Standalone companies have little incentive to change their processes to accommodate another company down the line. So, for example, if there are delays in finalizing the label language, the translation company or printer may not be able to expedite their work to get things back on track. And as long as they meet the terms of the contract, the sponsor would have no leverage or recourse. Fragmented oversight can also increase financial risk by not allowing partners enough visibility into timing to contract services further out at lower cost.

Finally, even patient compliance can be impacted by fragmented supply chain oversight through poor decisions that make dosing confusing. Dosing instruction language that may be clear to pharma professionals may be unclear to patients, resulting in unusable data as a result of unintended compliance.

Strategy 1

Consider finding a clinical trial supply partner who can either handle all aspects of your supply chain or who has extensive experience managing supply chain partners to help meet your speed and quality goals.

Is your "end-to-end" oversight really early-middle-to-late-middle oversight?

While the challenges of clinical trial supply may seem minor when compared to the peaks scaled in development, they are numerous — and related to everything that came before. In fact, many common supply chain issues are created, or augmented, by decisions made as early as pre-clinical investigations. Clinical trial supply partners who don't frequently collaborate with early-stage investigators will find it difficult to help guide decisions that drive steady trial progress. For example:

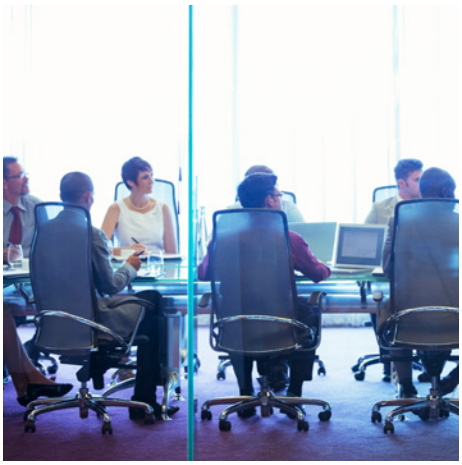
- Formulation can have a dramatic impact on everything from packaging and dosing to shipping and storage.
- Label text creation and translation can be started before final compound form is known, to help avoid last-minute delays.
- Understanding how drugs are classified around the world and what the regulations are about shipping them while still at the sourcing stage can potentially avoid downstream customs issues.
- Coordinating dose packaging and shipping containers early in the process can create significant savings — especially for cold chain therapies.
- Seeking more competitive suppliers early on can reduce ancillary and shipping costs as well.

If your clinical trial supply partner isn't able to seamlessly integrate with your drug development team early enough to have an impact, then their claims of end-to-end oversight should be seen as a promotion — not a promise.

Strategy 2

Consider partnering with a clinical trial supply company that has both pre-clinical and commercialization capabilities to start critical downstream tasks sooner.

Multiple supply chain partners: are they enhancing security or eroding it?



Pop quiz time: which introduces more risk to your clinical trial?

A: Partnering with individual specialists for labeling, packaging, distribution, etc.
B: Partnering with just one or two partners to handle everything

Most would quickly answer that B increases risk, citing the "all my eggs in one basket" school of thought. But that just might be one of the most dangerous fallacies of modern business. Complex supply chains do better with fewer links. Not because more links increase complexity, but because more links increase risk. Let's look at what that means in practice.

Downside risks:

While a supply chain of specialists sounds good, it increases your risk in at least four important ways:

- Without accountability for downstream activities, there's no incentive for upstream companies to work beyond their agreement to help solve issues that could surface later in the process.
- Different methodologies or even different definitions of similar terms can increase delays and add confusion.
- Handoffs between companies are also opportunities for mistakes, oversights, liabilities, and rework.
- Any slowdown that does occur may ripple downstream and cause you to miss your scheduled timeslot with another specialty provider.

Upside risks:

A long supply chain limits upside potential. Every company you work with requires a contract that needs to be negotiated, a system that needs to be integrated, and activities that call for oversight from someone in your organization. The time and cost to manage all of these will exacerbate an already slow, expensive endeavor. Furthermore, working with a long chain also eliminates the possibility of pooling supplies across projects, linking databases across phases, and earlier sharing of information to speed up downstream processes.

The other take:

On the flip side, working with just one or two larger companies that are experts across the clinical trial supply continuum can reduce risk by design. A global partner will have multiple locations that add redundant capabilities, offer global storage options to speed up shipping, and maybe even offer currency or tax savings by leveraging operations in different regions. Finally, with a short supply chain, the same company becomes responsible for most of, or all, the processes and has a strong incentive to reduce cost and complexity — and proactively solve issues before they crop up.

Strategy 3

Consider working with a clinical trial supply partner who can reduce risk by having multiple locations in several regions.

A strategy for keeping everything in control

Regardless of whether you settle on a short supply chain strategy or a long one, there will be multiple partners to coordinate because there are multiple facets to a clinical trial. At the very least, you're likely to have a CRO to run the trial, a CDMO to manufacture the therapy, and a clinical trial supply expert to link them with trial sites, investigators, and patients.

While each partner can be trusted to handle their role efficiently, it's common for mistakes to happen where they intersect. Different approaches by companies with different priorities often creates problems, even if everyone is paying attention. And, as mentioned at the outset, everything in a clinical trial is interdependent.

- The CRO will need insight into the flow of drugs to the sites, or directly to patients, to manage expectations and maintain compliance.
- The CDMO will need to know whether product is running in short supply and whether they need to plan to restart production.
- The Clinical Trial Supply company will need to coordinate with the CRO and CDMO to ensure information and product are flowing smoothly to all parties.

The key to keeping your trial running smoothly is a single Clinical Supply Chain Manager with oversight across the entire manufacturing process.

A robust Interactive Response Technology (IRT) platform can help everyone hit their milestones, but it has limitations. While user-acceptance testing ahead of the trial can help confirm the system will perform the functions you require, it's equally important to ensure the platform is properly programmed to handle major functions such as randomization, per-patient inventory management, and information sharing. You can't forecast correctly without real-time feedback. Of course, an IRT cannot be the final answer no matter how advanced it is, because mere software will not be able to course-correct if/when elements of the study slip off-plan.

The key to keeping your trial running smoothly is a single Clinical Supply Chain Manager with oversight across the entire manufacturing process. With that frame of reference, your manager can easily integrate labeling, packaging, distribution, patient dosing, and data gathering activities. Additionally, since all IRTs work on fundamental principles, it's helpful for your manager to have expertise in IRT set-up to help ensure it meets your program's needs and is programmed effectively. Finally, he, she, or they, should be well versed in partnering with clinical sites to ensure the human side of the trial is properly represented and managed.

Strategy 4

Consider having your Clinical Supply Chain Manager embedded within the CDMO to ensure oversight across manufacturing, IRT activities, and integration with clinical sites.

Conclusion

Clinical supply chain management is all about minimizing risk, cost, and time. While some companies might have you believe you have to sacrifice one to get the others, the right partner can find ways to deliver all three. Thermo Fisher Scientific is uniquely positioned to streamline clinical trials because of our end-to-end capabilities, deep expertise, unique approaches and technologies, and unmatched personal service.

Contact us to learn how Thermo Fisher Scientific can simplify and streamline your clinical trial supply.

About us

Thermo Fisher Scientific provides industry leading solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With unwavering commitment to service, science and process engineering, our clinical services team is powered by people with an exceptional commitment to quality and unrivaled expertise. We are exclusively focused on serving the packaging and distribution requirements of clinical trials across the world. Whether planning, packaging, labeling, storing, or distributing the important supplies needed to perform clinical research, we are committed to delivering the highest level of quality, performance, reliability and sustainability standards through our Patheon Fisher Clinical Services[SM] offerings.

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