N-SIDE

WHITEPAPER

End-to-end clinical supply chain optimization helps bring drugs to market faster

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There is immense pressure on the pharmaceutical and biotech industries to decrease clinical research timelines and accelerate time-to-market for important drugs. As we meet the demands of a growing global population and develop new kinds of therapeutics, the burden on the clinical trial process grows.

Thankfully, there are ways to speed up the clinical trial process.

Using advanced analytics, it's now possible to quantify risk, identify bottlenecks, and model and test the impacts of decisions on the entire clinical trial supply chain.

At N-SIDE, we've helped optimize over 10,000 clinical trials to accelerate timelines and reduce costs. We call this process **end-to-end clinical supply chain optimization.**

Unnecessary drug overage leads to wasted time

Drug waste is a necessary evil in clinical trials. In order to avoid stockouts that threaten patient health and the success of the trial, extra drug must be manufactured and kept close at hand, just in case.

These days, 55-75% of drugs are wasted in an average clinical trial. And as trial complexity increases, so do wastage rates.

That's because overage is built into each stage of the clinical trial supply chain. A shortage in any part of the process — drug substance (DS) manufacturing, drug product (DP) manufacturing, sourcing, depots, local clinical trial sites, etc. — could ultimately lead to missed dispensing for patients. As a result, every team needs a safety buffer in order to avoid becoming the bottleneck.

The more complex the trial, the more moving parts in the supply chain, the higher the overall wastage rate. All that extra DS and DP takes time to manufacture, extending trial timelines and eating up resources that could be used for other research.

However, while some overage is always necessary, the level of waste in most clinical trials today is much higher than could ever be needed, even if every initial estimate of recruitment speed, patient dropout, patient weight, and titrations turns out to be incorrect.

There are two main reasons why waste levels in clinical trials are higher than necessary:

- Overage is estimated based on rules of thumb or comparable past trials, and not calculated as an output of demand forecasts.
- Decisions about necessary safety buffers throughout the supply chain are made independently by each team, rather than holistically.

When decisions are made in a vacuum, opportunities for efficiency disappear. Take lot-to-study allocation, for example. Which DP lots do you package for a particular trial? One stakeholder may want to allocate the lot with the closest expiry date, while another might want a lot with a longer expiry to avoid the possibility of kits expiring.

Each stakeholder is attempting to maximize an individual KPI, but without information about production and trial supply, the best global solution for the sponsor cannot be identified. Lost opportunities like this one add up.

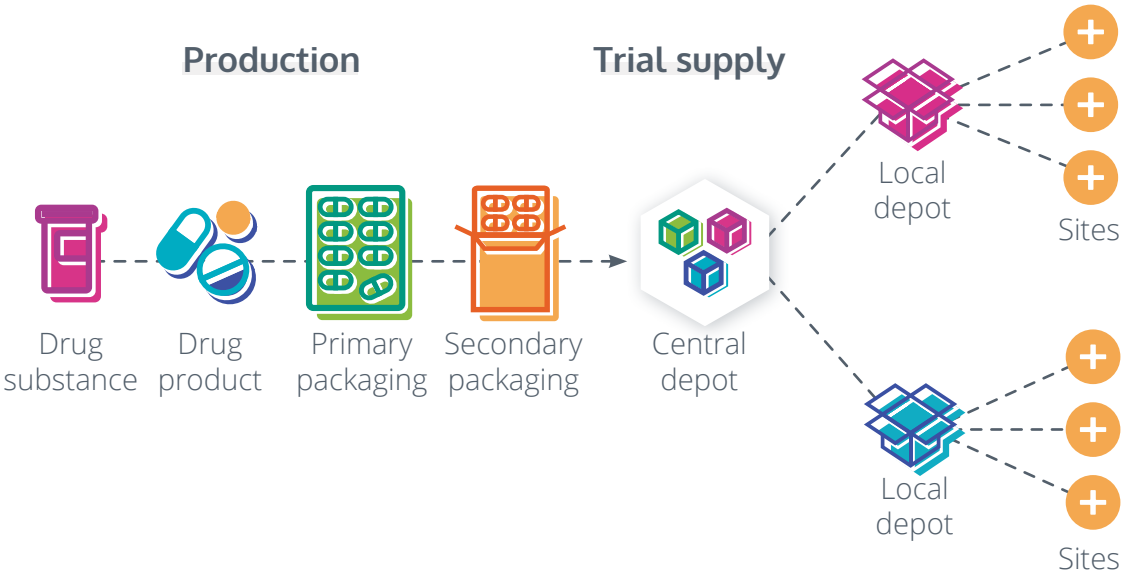
There is another way. End-to-end optimization involves breaking down silos and bringing visibility to the whole clinical trial supply chain to achieve cross-department alignment. It allows trials to be planned more accurately and more efficiently, reducing waste, freeing up manufacturing resources, and enabling new trials to be started faster — all without impacting patient safety.

Understanding the end-to-end supply chain

Clinical trial supply chains are deeply interconnected. Decisions made at the trial site impact decisions made in manufacturing, and vice versa. Unfortunately, most teams throughout the process work in silos, with very little data about what's happening upstream or downstream.

The solution is understanding the clinical supply chain as a whole. That involves connecting data silos, enabling greater sharing and feedback of information, leveraging real-time clinical trial data, and producing an accurate simulation of the entire clinical supply chain.

Step one is establishing a single source of truth shared by the whole supply chain, from manufacturing to clinical trial supply and clinical operations. This is usually a software system that all stakeholders can use to access up-to-date data and get an overview of the entire production planning and trial pipeline.



Making optimal decisions to reduce waste

With an end-to-end view of the supply chain and accurate data throughout, teams can make better decisions that minimize required overage. Advanced analytics tools like those provided by N-SIDE help support these decisions by modeling their impacts and analyzing uncertainty.

Which decisions should be optimized?

On the manufacturing side, optimization should address lot-to-lot and lot-to-demand allocation, lot sizing and timing, and clinical trial-specific constraints like the drug stability plan. This typically reduces manufacturing waste by 20-40%.

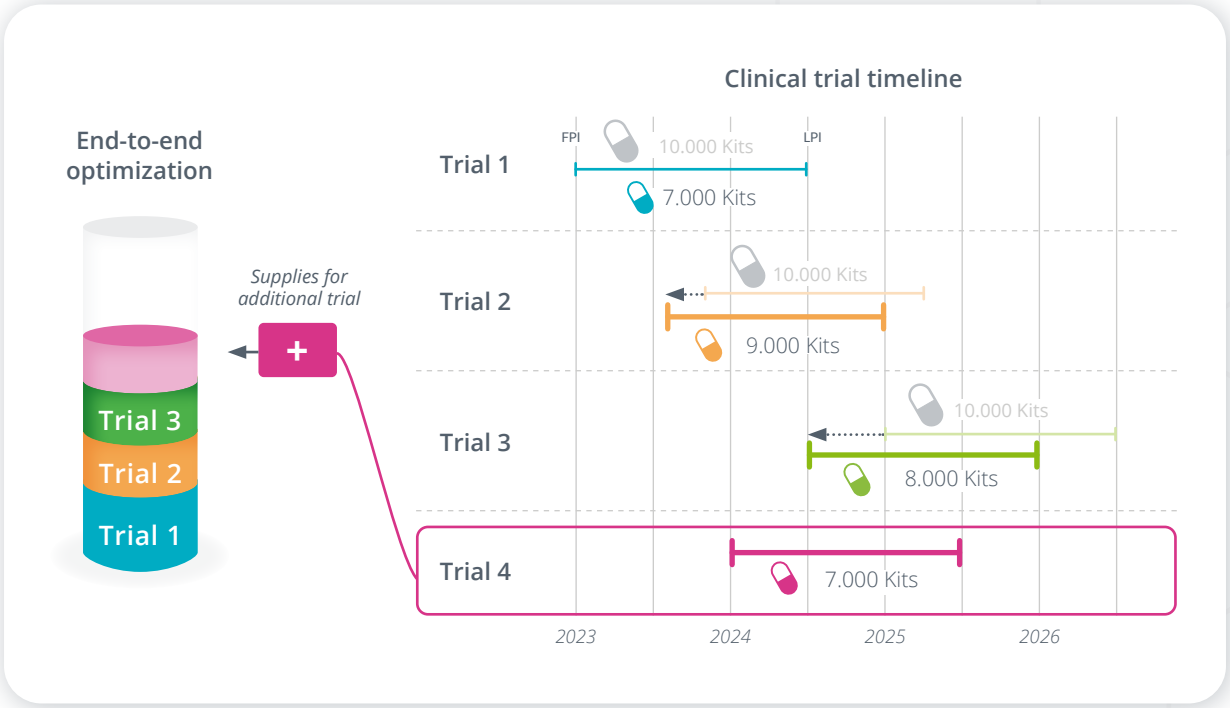
On the clinical trial supply side, protocols can be designed to be more supply-friendly, while at the same time ensuring patient and site centricity. For example, the kit design can be optimized alongside vendor selection, IRT configuration, network selection, and country selection. This can lead to a clinical trial-specific drug waste reduction of 20-60%.

Optimization doesn't just impact individual trials. By reducing drug waste and manufacturing needs, more DS and manufacturing capacity can be allocated to other projects. In fact, the same technologies and professional services that enable the optimization of individual trials can also be used to optimize production and supply across entire drug development programs, unlocking even more opportunities for increased efficiency.

Reducing drug waste has a direct impact on clinical research timelines. When less DS, DP, and IMP are required, research teams can:

- Open sites sooner
- Establish additional depots
- Accelerate recruitment
- Increase enrollment levels
- Move up trial start dates
- Allocate excess DP and budget toward additional trials

The ripple effects of these benefits carry forward through subsequent trials. The optimization of one trial enables future trials to start earlier, and eventually for the drug to come to market — and start helping patients — ahead of schedule.



The N-SIDE Suite: an end-to-end optimization solution

N-SIDE offers a SaaS solution and professional services to help the pharmaceutical and biotech industries optimize their clinical supply chains. We work with 50% of the world's top 20 pharma companies and have optimized drug waste in over 10,000 trials — all without ever having a trial paused due to drug shortage.

N-SIDE's expert consultants help our clients identify different levers for optimization based on the specifics of each clinical program. They reach these conclusions with the help of the N-SIDE Suite and its two advanced analytics applications: the Production App and the Supply App.

The Production App helps identify bottlenecks and allocation constraints in manufacturing and enables risk-based decision making to solve issues.

For example, optimizing DS to DP allocation could lead to solutions such as unfreezing smaller batches of drug substances to extend shelf lives. This approach allows the trial to meet real-time needs and move towards smaller manufacturing lots. Trials will then have the right amount of drug with the required shelf life at the right time, rather than drug products expiring unused.

Various production scenarios can be modeled to check viability and predict the impact of decisions (such as lot pooling, lot sizes, outsourcing, stability planning, and investment in new resources) on waste levels.

The Supply App helps clinical trial supply managers understand the demands of each trial so that the overall trial design can be optimized to minimize overage while ensuring patient service levels and cost-efficiency.

Before the trial begins, the Supply App simulates possible outcomes while factoring in uncertainty, then recommends minimum overage levels that still ensure each patient gets their doses on time. Then, during the trial, real-time data is used to monitor and re-evaluate the supply strategy to ensure it remains optimal throughout the trial lifecycle.

The Production and Supply Apps are interconnected. Data from each feeds into the other, so that the head always knows what the tail is doing, rather than each team making siloed decisions based on rough estimates.

For example, the evolution of DP demand can be modeled for all clinical trials that share the same DS. Areas of peak and low demand can be easily identified, and an overall picture can be formed quickly, showing how DS will convert to DP over time and how and where it will be allocated. This leads to accurate and granular cost analysis for each drug category.

With the N-SIDE Suite, program and study managers can always access the data they need to make educated decisions. Stakeholders at every part of the trial can offer improvement suggestions as the trial advances, forming a culture of collaboration.

Importantly, the N-SIDE Suite provides transparent, explainable recommendations, allowing each team at each part of the supply chain to trust the numbers they're using to make decisions. And because the N-SIDE Suite was developed specifically for clinical research, built-in tools let stakeholders control access where necessary for blinding.

LEARN MORE ABOUT THE N-SIDE SUITE

ABOUT N-SIDE

N-SIDE is a deeptech company that empowers organizations in the life sciences and energy sectors to make better decisions and optimize the use of critical resources.

We're doing so by combining deep industry expertise with applied mathematics and artificial intelligence into easy to use and cutting-edge software that transforms uncertainty and complexity into deterministic outcomes.

In Life Sciences, we streamline the clinical supply of pharmaceutical and biotech companies by accelerating clinical plans, mitigating risks and curbing drug waste.

In Energy, we accelerate the transition towards renewables and electrification by enabling leading grids and market players in making better, faster and safer decisions.

N-SIDE is ranked among the Best Workplace™ of the Great Place to Work® Institute Belgium and is also a certified B Corporation™.

For more information, visit **www.n-side.com**