

Optimizing a vaccine trial

Context

One of N-SIDE's biotech partners was about to initiate a **Phase III vaccine trial for a respiratory disease**. The trial was going to recruit 12,000 patients over 3 months, in more than 100 sites worldwide, with a 1:1 randomization between the vaccine candidate and the placebo.

Our partner identified that their **overage** on vaccine trials was incredibly high: **over 500%**, the equivalent of a **waste level of 80%**. Several months before first patient in, the sponsor and N-SIDE started collaborating and were given the challenge to reduce that number.

Analysis of the situation

Why do vaccine trials have such high waste levels? What are the characteristics we should consider and pay attention to? N-SIDE's analyses of vaccine trials gave some good answers to these questions.



1. Fast recruitment

Contrary to popular belief, fast recruitment is the main cause of waste in vaccine trials for multiple reasons:

- There is a need for **high buffers** to cover the possibility that one site could recruit over 20 patients per week.
- These patients will not specifically be recruited on a 1:1 basis at site level, due to **competitive recruitment**.
- The competitive recruitment could also lead to a potential **imbalance at depot level** in between the two treatment arms. We could end up with 60 patients on active and 40 on placebo in Brazil, or the opposite. But, due to long shipping lead times, we have to plan for depot inventories that cover both worst cases.



2. One dispensing visit and short screening period

There is only **one dispensing visit** and a **short screening period**. With a screening period of this length, the site buffers should cover worst-case recruitments to avoid missing patients. And, as there is only one visit, there is no chance for patients to consume the remaining site inventories after recruitment is over.



3. Shipping lead times

With fast recruitment and long shipping lead times (7-12 days from depot to site, 30-90 days from depot to depot), site inventories will need to be high. There is also little chance to send more than one shipment per depot, meaning that **depot inventories need to be stocked up** to cover worst cases. As adapting depot stock according to real-time recruitment is not possible, in the scenario where 1000 vials are dispatched to Brazil but only 100 patients are recruited, 900 vials would be lost.





4. Shipment boxes

This trial intended to ship syringes in **boxes of 10 units** to sites and depots, which also increased the waste.

Optimization and proposed solutions

Our partner built a **digital twin of their clinical trial** using the N-SIDE Supply App as soon as they received a protocol draft. This allowed them to **test multiple what-if scenarios** and see how the trial would react months before it actually started, **demonstrating a proactive approach**. This technology can be highly valuable in preventing fire fighting within the industry.

They tested a **geographical stratification** on patient randomization, instead of having a global block. This **reduced** the number of syringes needed **by 14%**. With **regional stratification**, we learned that there wouldn't be any imbalance at the depot level. The sum of all patients supplied by a depot would always be on a 1:1 proportion between both treatment arms.

They also tried a **site-level stratification** which, due to the high expected number of patients per site, was feasible according to biostatistics. With this level of stratification, they were able to **reduce quantities by 22%** instead of 14%.

Our partner also used the Supply App to identify the **best possible shipping box size** for their vials, which ended up being 3 instead of 10. Even though it increased their packaging costs, the **amount of drug saved (12%)** strongly counterbalanced those costs.

Thanks to numbers from the Supply App, they successfully **negotiated shorter shipping lead times** with their CMOs. Our partner was also able to convince their clinical operations team to cap weekly recruitment per site. The latter was eased by showing the team that **over 10,000 vials would be saved** by this action alone.

Their production planning (timing and quantities of packaging/labeling), release frequency, and depot shipments were also optimized by the Supply App, thus **significantly reducing their overage**.

Global impact

Taking **decisions prior to the start** of the trial has a massive impact on drug supply. This is even more true with fast-paced studies such as vaccine trials. **Quantifying the impact** of those decisions through technology and analytics is therefore essential. Manually estimating the overage is a dangerous and wasteful practice, especially when **optimization solutions can recommend** the right value.

Thanks to data and optimization, our partner was able to **massively reduce the drug waste** in their vaccine trial. All in all, the overage could be reduced **from 500% to 140%**.

[CONTACT US](#)

