

The hard balance between a short shelf life and low drug waste

Context

One of N-SIDE's recent partners was about to start a trial with a drug that would **only have 12 months of shelf life**. They would then get enough stability data to progressively extend it to 15 and 18 months in the following year, up to a maximum of 24 months.

Due to packaging & labeling timelines of 3 months, they would have to start recruitment with only 9 months of remaining shelf life. Updated stability would only come a quarter after FPI (First Patient In).

Our partner was struggling to accurately **assess the impact of short expiry dates** on their planning decisions (timing of releases, quantities, overage per release, expiry extensions). They had tried using tools such as Excel or forecasting systems, but these were not able to accurately represent the impact of expiry replacements on planning. Our partner would constantly end up having either too little drug, or way too much waste.

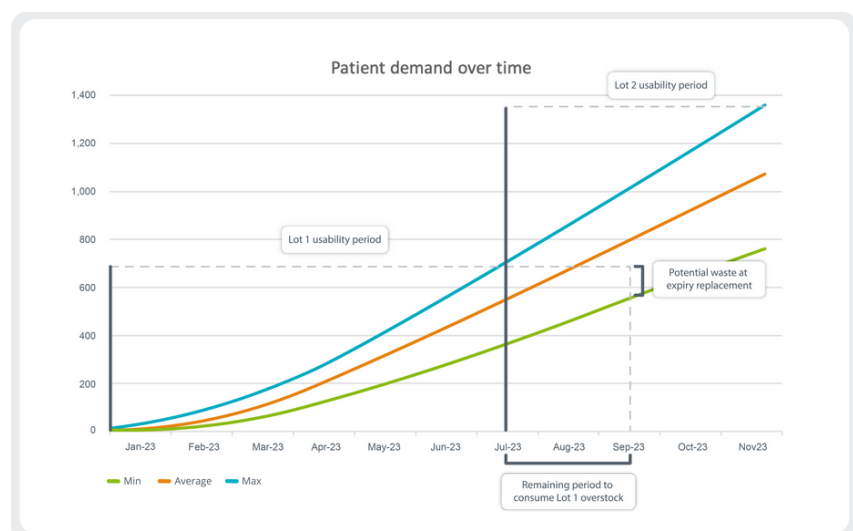
They didn't know how to plan for manufacturing, whether to re-label for expiry extensions, or whether it was safe to even initiate the trial. The visit interval was rather long (quarterly visits), further reducing the usability period of the drug. Overall, they expected to reach an **overage of around 300%**.

Analysis of the situation

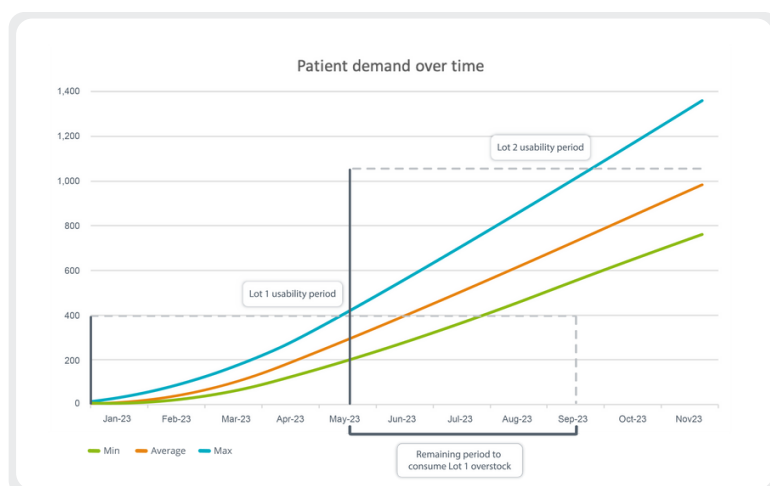
Understanding how **shelf life impact drug needs** is a complex question in clinical supply planning. The graph below illustrates it in a simple manner. It represents a demand curve for a specific treatment in a clinical trial. As recruitment, titrations, and drop-out are uncertain, a minimum and maximum demand curves are also considered. The vertical bars represent the release dates, while the dotted lines represent the shelf life and corresponding expiry dates.

With Lot 1, we want to cover the **worst-case demand** (blue line) until the next release, six months later. Lot 1 will be released with a shelf life of 9 months. If the **actual demand** is lower than expected (green line), we only have 2 months between the release date of Lot 2 and the expiry date of Lot 1 to consume leftovers, which will lead to **potential waste**.

The higher the uncertainty on IMP consumption is, the higher the potential waste due to expiry replacements will be, as we would need to cover more extreme cases, often ending up with a lower demand than expected.



In this second scenario, we **shifted the release of Lot 2 from July to May**. Let's see what happens here:



- The required worst-case coverage of Lot 1 is lower than in the previous example (400 kits instead of 700 kits).
- We now have 4 months to consume potential leftovers, instead of 2.
- There is statistically no waste due to expiries, except maybe for buffers at sites that did not recruit patients.

The two examples are from the same clinical trial, and they will have different amounts of waste on Lot 1. Only a **system that simulates the supply chain** is able to make this kind of assessment. Luckily, this is part of the N-SIDE Supply App core optimization algorithm.

N-SIDE's solutions **simulate the uncertainty of the IMP demand**. They also simulate the supply chain all the way through expiry replacements, providing an **accurate assessment of the waste these events cause**, based on the manufacturing/packaging strategy that is implemented.

Optimization and proposed solutions

With the help of N-SIDE's solutions, the client **analyzed multiple strategies** that could make the supply chain more efficient despite the short shelf life. As illustrated before, the frequency of manufacturing/packaging is one of them. Despite the willingness to only manufacture twice a year, numbers showed that **manufacturing 4 batches in the first year** would strongly reduce drug waste in the trial. The **overage would be cut in half, saving \$6.7M in unnecessary manufacturing, packaging, labeling, and shipments**. Another suggested idea, discussed in collaboration with the Clinical Operations team and CRO in charge, was to match the country initiation with the stability plan. Concretely, countries with longer shipping lead times, such as Brazil, would only be initiated after stability reached 12 months.

The N-SIDE Supply App also optimized the release timing, quantities, distribution to depots, and the configuration of the IRT system to **keep drug waste under control** while ensuring all patients get their treatment.

Global impact

Overall, the **overage of the trial fell below 80%**. With the ability to optimize their supply chain, and make data-driven decisions, the supply chain team was able to influence decisions outside of their scope. The country opening dates were discussed with clinical operations, and the manufacturing frequency with CMC. Thanks to N-SIDE's simulation and optimization algorithm, they had the right amount of drug at the right time and place and they felt **more comfortable in the management** of this complex trial's supply chain.

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