Clinical trial supply planning

Go Beyond Forecasting with Risk-based optimization

WHEN LOOKING INTO FORECASTING FOR CLINICAL TRIAL SUPPLY, YOU WILL PROBABLY INTERPRET THAT MOST OF THE FORECASTING SYSTEMS PERFORM OPTIMIZATION. WHILE FORECASTING INTENDS TO PREDICT FUTURE EVENTS, ***OPTIMIZATION AIMS AT MAKING A TASK AS EFFICIENT AS POSSIBLE BY PROVIDING THE BEST DECISIONS BASED ON A ROBUST MODEL****.*

So, what does clinical trial optimization and efficiency actually mean for your supply chain? And ***how can we distinguish traditional forecasting systems and risk-based optimization solutions when both types hide behind the term "optimization"?*** The main differences between these two are summarized as follow:

	Forecasting system	Risk-based optimization
Main KPIs (future demand, recruitment, etc.)	Average forecasts	Robust forecasts (with min-max values)
Risk assessment	✕	At all stages of the Supply Chain
Patient service level	Not measurable	Ensured by optimization
Waste level/overage (%)	Input	Output
Impact of trial design on drug waste	✕	Measured
Time to market acceleration	✕	Measured

Forecasting system and Risk-based optimization comparison table

Risk-based optimization ensures a safe supply chain, from CMC to patient, with minimal drug waste and budget.

Given that patients are at the heart of clinical trials, it is imperative to assess the clinical trial uncertainty as best as possible. Therefore, one of the most significant features of risk-based optimization is ***risk assessment***.

What risk am I encountering if my next batch is delayed by two months, and where will that risk appear? How do I know that I am shipping enough drug to Brazil? Or what enrollment rate that shipment will be able to cover? Forecasting systems won't answer these questions for you.

By considering all potential uncertainties of a trial, such as recruitment timing and location, weight distribution, titrations, etc., ***a robust model will define the probability of certain events happening***.

N-SIDE's Model

Risk-based optimization therefore assesses risks ***at all stages of the supply chain***. From the ***earliest stages of manufacturing to patient dispensing***, risk-based optimization increases visibility on any risk, whether it is a patient missing a kit at site level or a global drug shortage at a depot.

Accordingly, ***risk-based optimization quantifies, locates and assesses the probability of a risk of drug shortage in the supply chain created by events such as*** batch delays, increased lead times to depot/site, faster recruitment, increasing buffers on site, API unavailability, etc.

This risk assessment is complemented by the fact that the ***overage**** ***is an output*** from risk-based optimization. This optimized overage will be the lowest possible overage that covers all risks.

Forecasting systems request this number as an input, but do not give you visibility on the risk level associated to this decision. How can you know, when entering the overage manually, that that your patients are safe?

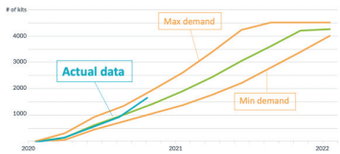
Can you really call it "optimizing" when the overage is entered as an input?

Having the overage as an output opens the door for even ***larger optimization analyses***. Thanks to this feature, you can perform strategic ***trial design optimization***, even when the protocol is still a draft. Indeed, you can assess the overage needs and budgets associated to different decisions, and therefore perform actual clinical trial optimization, as illustrated in the case study below.

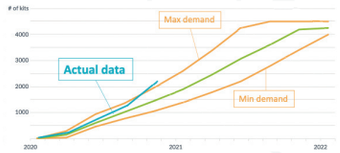
* *Overage can also be defined as overstock or additional waste (=# kits wasted/patient demand)*

Decision*	Optimized Overage
Baseline	75%
Updated visit schedule	62%
+ Optimized Kit design	51%
+ Updated network (country selection + removal of some depots)	46%
+ Direct to patient	32%

Finally, by ***having the overage as an output, you can assess the robustness of your strategy***. For all KPIs such as demand, drop-out, recruitment, etc., you get a ***visibility*** on the minimum and maximum rates that your strategy covers. Thanks to ***N-SIDE's monitoring dashboard*** and its IRT integration, you can easily check how ***real-time*** events compare to the forecast, and whether your supply strategy is still valid today or needs to ***be re-evaluated***.



Actual demand is slightly faster than average demand, but the strategy is still valid.



Actual demand is outside of the strategy coverage threshold; therefore, the strategy needs to be re-evaluated.

Risk-based optimization has many other additional values, from requiring less data entry, as some of it is given as an output, to optimizing the ***depot resupply strategy by considering lead times, shelf life and demand uncertainty***. And includes opportunities for clinical supply chain and manufacturing to never be a bottleneck, therefore providing measurable acceleration of time to market.

* *Scenarios are cumulated*

The N-SIDE Suite for Clinical Trials is the only end-to-end Risk-based optimization system available on the market, with a track record of over ***1000 trials optimized per year***, and a proven ***reduction of drug waste*** and ***trial budgets by an average of 30%***, by always ***ensuring 100% patient service level***.