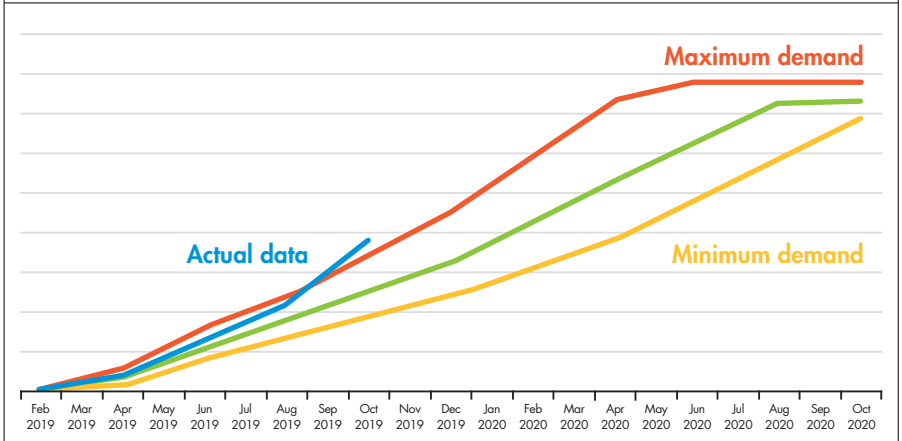
Beyond forecasting with real-time monitoring

Using risk-based optimisation and harnessing the power of real-time trial data, the **N-SIDE** Suite for Clinical Trials helps clinical trial supply managers in decision-making from strategy to operations. A case study with N-SIDE and **CSL Behring** demonstrates the benefits of implementing supply optimisation and real-time monitoring dashboards.

Now more than ever, using the right suite of tools in clinical trial supply management is essential to driving reduction of drug waste, excessive shipments and rework, while ensuring no risk to patients receiving their medication on time. The workload to gather, process and understand all of the data required in managing clinical trial supplies is significant. Making the situation even more complex, diverse project stakeholders often are using different systems and have different focus. Being able to have an up-to-date view on the information used for clinical supply chain assumptions, forecasts and real-time data is critical but challenging.

N-SIDE Suite for Clinical Trials can address these challenges. By mixing different advanced analytics techniques such as risk-based optimisation, data aggregation, machine learning, business intelligence visualisation and integration of real-time data, project stakeholders may take safer and more efficient decisions throughout the trial life cycle.

Figure 1: Forecasted patient demand – initial forecast



Need for risk-mitigation actions can be quickly assessed by comparing the forecast to the real-time trial data.

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Jacques Parlongue, N-SIDE

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Risk-based optimisation benefits

One key element is having risk-based optimisation so that the identified supply strategies do not jeopardise patient dispensing visits. Risk-based optimisation takes the guesswork out of achieving the minimal level of overage needed to safely supply a clinical trial. Different scenarios can be compared and the level of drug waste known for each. This can help drive decision-making during protocol design with fact-based discussions on the waste impact.

For ongoing trials, optimisation can help with being prepared to react to change with the best-fit strategy. By preparing what-if scenarios for faster or slower enrolment, different drop-out rates and more, the clinical supply manager is ready to cover different scenarios agreed with the trial team, already having a view on what changes need to be made and what would be the impact to cost, risk and waste levels if the supply strategy should be later updated to cover some alternative clinical demand. In addition to proactive risk management, using the N-SIDE Suite for Clinical Trials decreases supply costs, on average by 30%.

Turn data into actionable insights

Smart data aggregation and business intelligence visualisation increases efficiency, and enables analysis and communication across the organisation. By having all clinical supply chain forecasts and real-time trial data in one suite, global views across the portfolio are available, providing a view on budgets and timelines. It also permits drilling down to targeted information to answer specific questions regarding depot and inventory management or risk management, for example. Insights can easily be shared and communication supported with simulation results.

Also essential is being able to quickly and easily leverage real-time data to support decision-making. Assessing whether your clinical and supply forecasts are still consistent with real-time data is key to

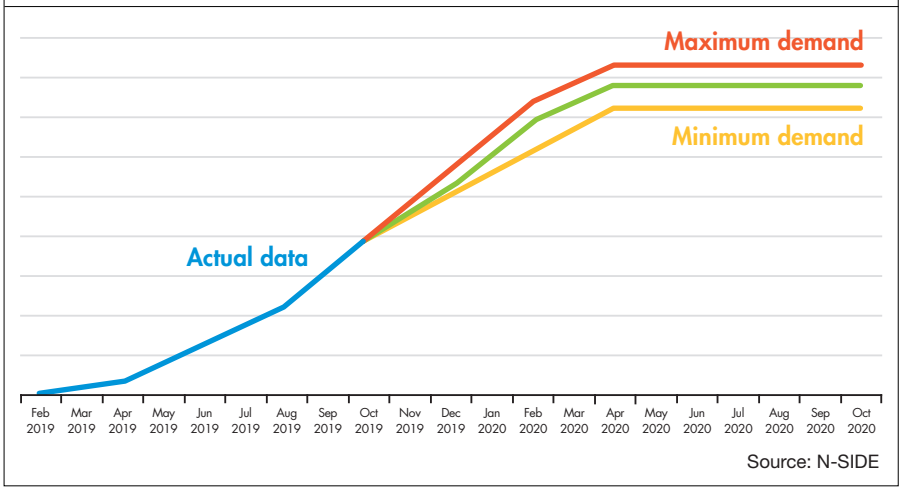
controlling the risk for patients while minimising study budget. If your trial planning needs adaptation, you will directly get the answers to questions such as:

- Is regional enrollment faster or slower than expected?
- Does a local depot need to be resupplied earlier than foreseen?
- Does the packaging plan need to be adapted regarding timing or quantities of releases?
- Are the site statuses aligned with the actual activity at each site?

By using simulations, a study manager is assessing the uncertainty expected on their clinical trial supplies. This means the study manager may visualise in a straightforward way the minimum and maximum demand covered by the current supply chain decisions. By situating real-time data in the context of the boundaries of the current supply strategy, the need for risk-mitigating actions can be quickly assessed, increasing reactivity and efficiency.

When it is time to update the supply strategy, it is important to consider the real-time trial data and the clinical assumptions for how the trial will continue. Taking both into account, using machine learning to combine the information based on the confidence in the clinical assumptions and the amount of data available at that point in the trial, improves accuracy and reliability. This allows the study managers to have the best information for their management of the trial.

Figure 2: Forecasted patient demand – actual forecast



In order to update the supply strategy, it is important to consider the actual trial data in order to re-forecast the demand and re-optimise the supply strategy. Doing so allows further reduction of waste, but mostly ensures the strategy is always robust enough to keep a 100% service level.

waste avoidance. Having the actual impact on cost, waste and risk quantified by the simulations was key in driving change.

CSL Behring clinical supply managers work collaboratively with N-SIDE strategic consulting services to optimise their supply strategy and be prepared for the unexpected. To manage uncertainty, key what-if scenarios are identified and simulated – considering all of the supply constraints and specific trial design – in order to be ready to react to changes in ongoing trials.

Working together on a high-stakes clinical trial, CSL Behring and N-SIDE have investigated a combination of different enrolment rates and manufacturing yields in order to be prepared for any event.

"Using N-SIDE supply optimisation on this high-priority study has allowed us to challenge and improve our standard ways of working to reduce drug waste and avoid stock-outs that could result in a missed patient treatment."

Patrick McLaughlin, CSL Behring

Case study

CSL Behring has benefitted from N-SIDE supply optimisation and dashboards in managing its clinical supply chain. This collaboration has helped avoid drug waste in trials by challenging the historical ways of working. Batch sizes, packaging frequency and packaging lead times have been reviewed and optimised, allowing cost and

When the enrolment rate exceeded even the highest clinical forecast and the manufacturing yield was less than the expected levels, the CSL Behring team was prepared to address this challenging situation. Thanks to an early collaboration and the implementation of a flexible strategy based on the investigation of worst-case scenarios, the trial is being conducted with minimal risk of a missed patient dose administration and at the lowest cost.

"Using N-SIDE supply optimisation on this high-priority study has allowed us to challenge and improve our standard ways of working to reduce drug waste and avoid stock-outs that could result in a missed patient treatment," says Patrick McLaughlin, senior director, clinical trial supply and IRT, global supply chain management at CSL Behring.

N-SIDE dashboards are also used by CSL Behring to monitor the trial. These dashboards allow an easy visual assessment to see if the trial is on track and within the safe boundaries of the current strategy. The data can be visualised at the country, depot and trial level to help identify the specific actions that need to be taken. By having the data that is required for monitoring automatically ready, and visualised in one place, saves time that was previously used gathering and preparing data for monitoring, while also increasing efficiency.

"With N-SIDE monitoring dashboards, our clinical supply managers work more efficiently. They are able to easily review real-time trial data in relation to their forecasts and identify actions to be taken to ensure sufficient inventory at clinical sites to meet patient needs. This enables clinical supply managers to focus on more value-added, customer-facing supply management activities," says McLaughlin. ●

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