

# Award-winning risk-based optimisation project

Sanofi's supply team has successfully implemented the **N-SIDE** optimisation solution, CT-FAST. The proven strategy led the team to become the proud winners of the 2016 Best Operational Excellence Award at the company's Global R&D Awards.

**T**he implementation of N-SIDE's CT-FAST solution resulted in the Sanofi clinical supply team moving towards an end-to-end optimisation approach and challenging standard practices. The results provide the optimal global strategy to take the best decisions throughout the entire supply chain according to the study specificities. With simulations, all of the inputs used as assumptions for the trial are made explicit and can be examined with the Sanofi clinical team. As is the case for most clinical trials all over the world, clinical assumptions may be subject to many changes, affecting supply chain planning. These changes may lead to supply chain inefficiencies such as budget increases and extra risk of patients missing a dose. Being able to proactively work on these clinical assumptions and assess the impact of potential changes is therefore key to safely and efficiently handling the clinical trial.

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– **Didier Basseras, vice-president of clinical supplies, Sanofi**

## Proactive risk mitigation

This approach involving use of simulations and optimisation led to the realisation of important key benefits. As Didier Basseras, vice-president of clinical supplies at Sanofi, says, “In a VUCA [volatility, uncertainty, complexity and ambiguity] world, simulations and forecasting are creating a tactical clinical supply chain, ensuring that each patient gets their medication on time.”

Managing risk is one of the main outcomes of using N-SIDE's CT-FAST solution. Using results from thousands of simulations that take into account the variability of potential occurrences during the trial, study risk can be identified. Knowing the timing, location and probability of risk events with information provided by the simulations, clinical supply managers are able to take actions proactively in order to mitigate risk and guarantee that patients will receive their appropriate treatment on time. In this project, the Sanofi



Members of Sanofi's clinical supply team with their award for Best Operational Excellence.

supply team saw a large reduction in firefighting and decreased stress levels within the team.

Increased collaboration across departments is another key benefit resulting from the CT-FAST implementation. Sanofi clinical supply managers use simulations results to support communication with other teams, including distribution, clinical, packaging and IRT experts. Strategic decisions, even before protocol finalisation, can also be investigated with simulations. Many 'what if' scenarios can be tested, and the quantified results for different scenarios facilitate communication and decision-making. In this project, the teams observed a shift in collaboration to an earlier time point in the trial, starting at trial concept. An overall increase in collaboration between Sanofi teams based on CT-FAST results has supported strategic decision-making; for example, with regard to time between screening and randomisation, country selection, stratification level and packaging design. The impacts of these decisions were discussed globally, taking into account clinical and supply impacts while ensuring patient safety. This global picture allowed faster agreement on the decisions and the optimal supply strategy to be implemented accordingly.

## Reduced waste and lower costs

Another added value of using N-SIDE's solution is decreased product waste. By implementing the optimal supply strategy for each trial while controlling risk, production planning is tuned to meet demand and the required overage to manage risk. However, the amount of overage needed for the trial is calculated precisely during the simulations in order to prevent any risk to patient dispensing. By planning for only the needed study overage – factoring in the protocol specificities, and distribution and IRT strategy needs – production plans are optimised for the study, which leads to drug savings.

In addition to selecting optimal production planning, earlier collaboration between Sanofi clinical and supply teams led to



choosing protocol designs that optimise use of product. This reduction in product waste allows production capacity to be used more optimally. As many biopharmaceutical companies face constraints due to limited manufacturing resources, this is a very important outcome of the project.

Decreased supply costs are another important key benefit of CT-FAST implementation, with an average reduction of about 20% in the cost of trial supplies. The optimised use of product is one aspect of these important cost savings. Especially for trials with expensive comparators, the cost savings are significant when the optimal supply strategy is implemented. Another component of the cost savings is distribution costs. With these optimisation results, the best balance for the trade-off between distribution costs and material costs is achieved, also taking into account the custom fees, which may be important for some trials.

### Boost agility

Using CT-FAST, Sanofi supply managers are able to quickly adapt to change. By running thousands of simulations, the results show the range of variability anticipated in the study. The optimal supply strategy will cover the variability inherent in the trial, such as enrolment rates and titration probabilities. Testing 'what if' scenarios allows the team to foresee what could happen in the trial – such as faster enrolment or lower drop-out rates – and plan for these possibilities. By leveraging real-time data from the IRT system, simulations are updated to reflect what is happening in the trial. In this project, the Sanofi team was able to update forecasts and identify appropriate risk management actions to adapt the strategy to deviations from initial assumptions.

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– Sylvie Noirault, head of clinical supply chain management, Sanofi

With the collaboration between Sanofi and N-SIDE, it has been possible to optimise the IRT settings for each study. Using CT-FAST results, the Sanofi supply team was able to quantify the impact of specific IRT settings and select the best strategy for each study. Moreover, this optimal IRT set-up is efficiently related to the study coverage, number of shipments, site inventories, study cost and the risk of a patient missing a dose. This global overview of the study is key for lean management of the trial and improved collaboration between all departments.

Gina Desbiens, Sanofi's head of business and operational excellence, adds, “This project is a great example of a lean implementation. It improves the added value of many human tasks and optimises the use of our drugs.”

### Top benefits of supply forecasting and optimisation

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Proactively mitigate **100%** of the risk of your patients missing a dose
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Set-up your **IRT** to best fit your trial specificities
- 

Anticipate trial changes & adapt your **supply strategy** quickly
- 

Improve **collaboration** between supply managers, clinical managers and project leaders
- 

Significantly drive drug **waste reduction**
- 

Decrease supply costs on average by **20%**

N-SIDE's solution for end-to-end supply chain optimisation.

### Going further with optimisation

The Sanofi team is moving forward with the global optimisation approach. One of the next steps in the project is to enlarge the scope of risk-based optimisation. Through collaboration with N-SIDE, the next goal is to integrate the full upstream process, from the optimised manufacturing of drug substance to the pooling of drug products and a safe but efficient allocation of the lots for the clinical trial portfolio. This end-to-end modelling will further decrease drug waste and allow even better management of the Sanofi biomanufacturing capacities. Furthermore, collaboration with R&D manufacturers and industrial affairs will be facilitated thanks to this improved drug substance/product planning based on the use of quantified and reliable data to assess different scenarios with a risk-versus-cost analysis.

“Optimising our drug forecast and production plan is key to ensuring the best use of our biomanufacturing capacities to provide medication to patients all over the world,” Sylvie Noirault, Sanofi's head of clinical supply chain management, concludes. ■

### Further information

Sanofi [www.sanofi.com](http://www.sanofi.com)  
N-SIDE [www.n-side.com](http://www.n-side.com)

