

Manage changes and control risk easily and quickly

Optimisation solution CT-FAST from **N-SIDE** rapidly tests and compares thousands of supply strategies, allowing clinical supply managers to improve accuracy and increase predictability.

Thanks to the assistance of advanced analytics such as optimisation, the clinical supply manager is better positioned to anticipate the unpredictable. Being able to select a supply strategy that is robust to changes is key, but is often very expensive. Optimisation enables changes to be taken into account while realigning initial assumptions to actuals. This allows the supply manager to control the risk easily throughout the study life cycle and the pharmaceutical company to decrease cost, leading to millions in savings.

Changes are a constant

Over the course of supplying a clinical study, factors such as drop-out rate, enrolment speed, and the sites and countries involved can change rapidly. Highly unpredictable demand translates into a lot of uncertainty and high costs to cover worst-case scenarios. Managing changes in this complex situation, while at the same time controlling the risk of an 'out of stock', can be a stressful challenge for clinical supply teams. However, using the right tool to facilitate clinical supply decisions can make life easier and result in significant cost savings.

“ With CT-FAST, Roche has been able to reduce overage, and find the optimal balance between distribution and material costs. ”

– David Volk, head, clinical demand & supply planning at F. Hoffmann-La Roche

How do the available solutions stack up?

Up to 80% of clinical trial supply teams still use spreadsheets involving lengthy calculations to manage demand uncertainty during ongoing trials. While this approach to controlling risk may be appropriate in the context of simple trials, troubles can quickly arise when dealing with complicated cases.

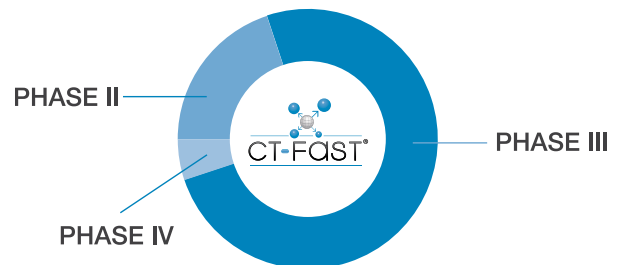
A very high overage is often used in order to ensure that no drug shortages occur. Without a reliable forecast, decisions may be based on a mix of experience, intuition and rules of thumb due to the uncertainty. Forecasting tools allow the users to compute a more accurate average package demand for a given trial. On top of this patient demand, additional overage needs to be manually added. Moreover, in order to consider the risk connected to the results, simulation or optimisation is needed.

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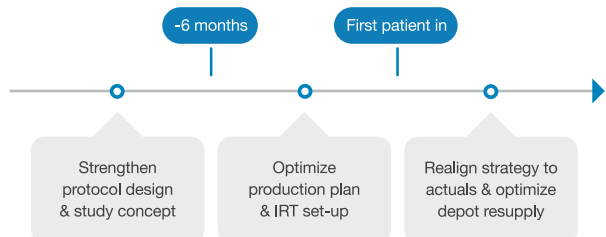
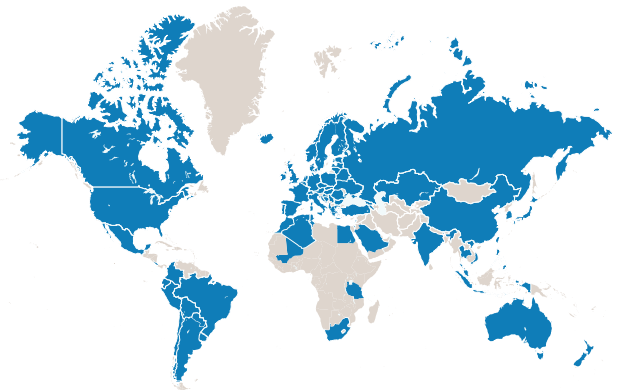
Top pharma companies already benefiting from CT-FAST

2 million USD

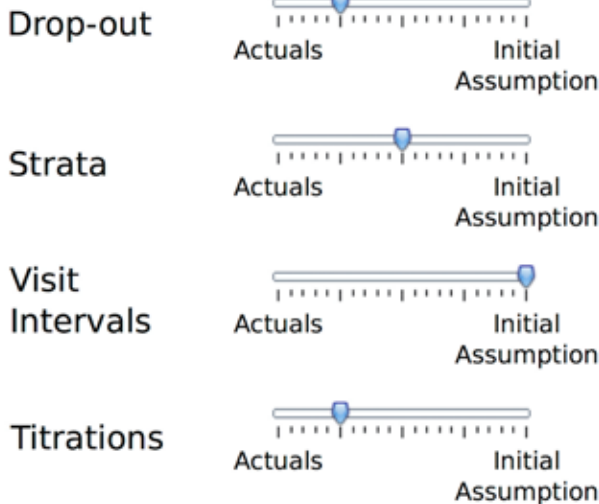
Average savings per trial



Worldwide reach of CT-FAST supply management



Optimisation added value throughout the trial.



CT-FAST allows you to leverage initial assumptions and actuals (from the IRT provider) to better manage the supply of your ongoing trials.

Regular simulation tools give an idea of the possible variability in the demand that can arise from randomisation or titration. They can also roughly assess the risk of one strategy. Testing multiple strategies is time consuming and typically this process is shortened by running a small number of simulations.

Optimisation tools go a step further. Solutions such as CT-FAST quickly test and compare a large number of supply strategies through performance indicators such as risk estimation, overage and number of shipments. Running thousands of simulations for each supply strategy yields results with a high level of accuracy. Areas of risk are pinpointed so they can be controlled.

Reports from the optimisation allow the supply team to assess different scenarios and decide on the most appropriate strategy. Because the outcome is trustworthy, the supply team no longer needs to counteract uncertainty with additional buffers on top of recommended stock levels. Quantified and robust results in the optimisation report facilitate cross-department communication.

Plan for the unforeseen

Even during the set-up phase, things can evolve quickly and assumptions may not be validated. Since decisions need to be made, optimisation can be used to analyse a multitude of scenarios and compare the associated cost and risk. Although many different situations could still occur, optimisation puts the supply team in a good position to consider alternatives and identify the best-fit strategy to cover the uncertainty and worst-case scenarios.

The two main deliverables of this phase – the production plan and resupply strategy (the set-up of IRT settings) – are interdependent. Being able to take this interdependence into account is a key strength of optimisation, as it achieves the right balance of shipping vs material costs. Furthermore, it enables testing of many “what-if” scenarios such as differences in enrolment and drop-out rate, and updates to the country list. The robustness of the production plan and resupply strategy is thus challenged, and an overall strategy can be chosen to minimise the impact of future changes. By accurately

choosing the robust strategy that optimises the cost while keeping risk limited, millions of dollars can be saved.

Learn from the past and anticipate the future

Once the study is underway, an optimisation tool has the power to re-evaluate the study constantly. Actual study data can be analysed quickly and utilised to improve planning over the initial assumptions. Both historical data from the IRT provider and the study assumptions are taken into account with an appropriate weight. This allows the supply team to easily consider the past and to plan accurately for the future.

Optimisation solutions are designed to address complex challenges. Take depot management: regional depots are usually a source of most of the risky situations and study overage. CT-FAST tests thousands of different shipment dates and quantities to provide an optimal depot supply strategy. Like the production plan, it can be re-evaluated as the study evolves.

“ Supplies forecasting requires disciplined planning. This is made even more difficult when your study designs are extremely complicated. It was (and still may be) a common practice to plan for worst case scenarios to minimise risk. The CT-FAST tool allows us to perform re-evaluations, using IRT data from our ongoing studies, to generate targeted production plans for the future. CT-FAST allows us to escape the world of expensive worst case supplies planning while working with an acceptable level of risk for our company. ”

– Jun Lee, clinical supplies project lead, Otsuka Pharmaceutical

Using the right clinical supply management solution to navigate change throughout the study life cycle results in easier and more informed decision-making. Optimisation helps supply teams to reduce overage and avoid stock-outs, saving millions in the process. ■

Further information
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