ALMAC

Partnering to Advance Human Health

Case Study

Statistical modelling identifies optimal supply strategy, leading to flawless execution

Every clinical trial follows a supply plan. But how can sponsors be assured that the plan is both optimal and flexible enough to reflect changing trial conditions? Through a combination of statistical modelling and continuous forecasting, Almac Supply Chain Managers helped one sponsor have the best of all possible worlds: minimised distribution and drug costs with no stockouts or patient dosing delays.

The business challenge: managing the distribution of expensive, pre-purchased supplies

A top tier global pharmaceutical company was preparing for a Phase III trial of a biosimilar immunology treatment and was under time and budget pressure to develop and execute a flawless supply plan. The sponsor was in a race to market, and the go-live date for the trial was set. In preparation, the sponsor had already procured enough of the expensive comparator drug to match its first three production campaigns for the investigator drug. Each kit cost over £120.

Challenges included:

- Would the supplies on hand be sufficient to meet patient demand with no stockouts?
- Could the supplies be used in time to avoid wastage despite the fact that they were due to expire in just eight months?
- Could distribution match demand, given that sites had limited space in which to store the patient kits?
- The sponsor wanted such assurances for two reasons:
  1) there was great uncertainty surrounding the Contract Research Organisation's (CROs) patient recruitment projections and;
  2) the sponsor had not outsourced Supply Chain Management before.

The Almac solution: advanced simulations to model risks

Almac worked with a business partner who specialises in advanced analytics to simulate various demand/supply scenarios. Almac's Supply Chain Management (SCM) experts ensured that the initial assumptions on which the simulation was based were accurate and detailed enough to support a robust model. Through Monte Carlo Simulation, the team tested scores of combinations of supply variables to evaluate the risks and costs associated with each.

They were then able to reject all strategies that bore any risk of stockouts and to zero in on the three most optimal strategies—those with the best cost/risk balance. Next, they performed a thorough analysis of the cost impact, time impact, and stocking requirements for each supply strategy to identify the best one to pursue. In the process, they identified the highest recruitment rate that the existing supplies could support and the highest volume of supplies that sites could manage.

The optimal strategy, as agreed upon by the sponsor, was then used to develop a pre-study drug supply forecast in Almac's SupplyWise™ forecasting tool. The forecasted enrolment rates were used to determine the appropriate trigger and safety stock/buffer levels for the Interactive Response Technology (IRT) resupply strategy. As the study progressed, the forecast in SupplyWise™ was updated weekly with actual patient demand metrics.

The client results: informed strategy prevents stockouts, saves £556k

Based on the output of the simulation model, and in consultation with Almac's SCM experts, the sponsor was able to select a supply strategy that presented an acceptable level of risk. As the sponsor's Manager of Clinical Trial Supplies noted, *"(Almac's) packaging and labelling expertise combined with the sophisticated scenario based simulation of clinical supply process made visible the potential effects of (our) decisions and requirements."* The trial team thus went into the trial with a high degree of confidence in its operational decisions. Supplies were being managed at a site and patient level, a degree of granularity that the sponsor had never previously enjoyed.

As the trial progressed, the feedback on product demand that was fed into SupplyWise™ consistently served to keep actual supply levels inside the optimal range. As it happened, recruitment went faster than was expected in the baseline assumptions, but because that exact scenario had been modelled, supply chain managers knew how to respond. By making slight adjustments to the quantity of kits in the distribution chain, they were able to ensure that there were no stockouts. Sites were not held back in recruitment, and no patients had to miss visits due to supply shortages.

In fact, it all went so well that through a combination of faster recruitment and close supply chain oversight, the trial was completed without the need to produce and acquire product for the last campaign. This alone saved the sponsor nearly £556,000.

To find out more about how Almac can support your clinical trial contact us now.

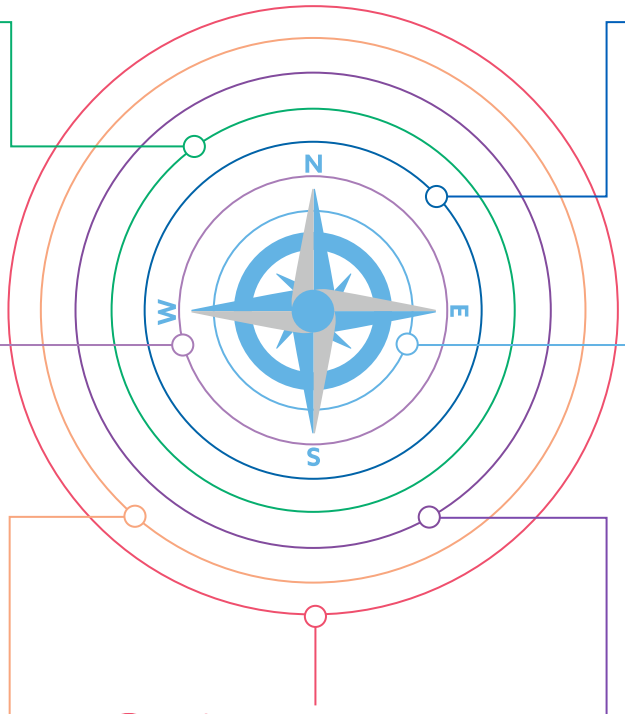
almacgroup.com

Almac Supply Chain Management Solutions -

Navigating the complexities of the Clinical Supply Chain

Forecast and simulation
Clinical material forecasting, forecast management and simulation tools along with SCM expertise, matches clinical supply to patient demand, ensuring optimised strategies to meet your trial needs.

Label development and regulatory vetting
Almac can oversee label text development, regulatory review, translation and artwork, ensuring that IMP labels meet clinical, regulatory, drug product and country specific requirements.



Inventory management
Supply Chain Managers continually monitor trial supply globally, trending study activities and adjusting future campaigns and material transfers to ensure that the right IMP is at the right place at the right time to meet study demand.

Temperature management solutions
Almac's innovative software program, TempEZ™, supports the full suite of Almac Temperature Services offerings, providing clients with a single central database to store temperature data while ensuring compliance to GxP and GDP regulations.

IRT Medication management
Supply Chain Managers consult on the medication management IRT design to meet study needs. They set, monitor and adjust inventory management levels and system expiry strategies to ensure optimisation of IMP while reducing distribution costs where possible.

Other services
Almac Supply Chain Managers can provide end to end management of investigator sponsored trials, provide pharmacy services and draft pharmacy manuals. They can also act as unblinded contacts for the site management of clinical supplies.

Bulk drug management
Supply Chain Managers convert finished good demand into upstream manufacturing and API requirements, working with capacity and lead time limitations to avoid downstream supply interruptions and reduce over production and bulk waste.

GET IN TOUCH

UK
Almac Group
(Global Headquarters)
9 Charlestown Road
Seagoe Industrial Estate
Craigavon
BT63 5PW
United Kingdom

clinicalservices@almacgroup.com
+44 28 3836 2436

US
Almac Group
(US Headquarters)
25 Fretz Road
Souderton, PA 18964
United States of America

clinicalservices@almacgroup.com
+1 215 660 8500

SINGAPORE
Almac Pharmaceutical
Services Pte. Ltd.
9 Changi South Street 3
#01-01 Freight Links Building
Singapore 486361

clinicalservices@almacgroup.com
+65 6309 0720

AM4391