

A new resupply strategy turns an emergency into an opportunity

Supply With Care™





A customer faced with impending comparator shortage, complicated by expanding enrolment, partners with Almac's Supply Chain Managers (SCM) to evaluate supply chain needs, assess potential risks, stretch supply and advise on global and regional clinical strategy.

The business challenge:

Impending product expiry, potential enrolment suspension

When Almac Clinical Services was called in to address an impending product expiry, the sponsor's situation with a Phase II trial was quite precarious.

The trial was comparing the safety and efficacy of the sponsor's Investigational Medicinal Product (IMP) to a comparator product at 74 sites across 13 countries. The comparator product was difficult to procure, and 100 percent of existing supplies were due to expire in 2 months. Replacement comparator product had been ordered, with quantities based upon an educated guess. Unfortunately, these materials wouldn't be available until 1 month prior to the expiration, leaving insufficient time to restock the supply network.

This scenario was further complicated by the need to boost target enrolment. This strategy would include the addition of 5 countries and an increase in enrolment on a site by site basis (each site was previously limited to enrolling and treating one patient at a time.)

The clinical operations team turned to Almac to manage the situation. They needed to know:

- Would the replacement comparator order be enough product to complete the trial, and accommodate an increase in target enrolment?
- If supply gaps are identified, what would be the most efficient and effective apportionment of supplies across sites and countries?
- Can sites be permitted to enrol more than one patient at a time?

Changing enrolment projections and adjustable dose levels (1-21 vials per dose based upon lab values) would make answering these questions difficult.



The Almac solution:

An optimised resupply plan

Almac Clinical Services immediately set about estimating how much of the comparator product would be needed and how the limited supplies should effectively be distributed. The goal was to minimise interruption to the study by acting swiftly and on the basis of facts.

Using Interactive Response Technology (IRT) data, the Almac SCM reviewed lead times and vial usage rates by country over the first few months of the study, and then used this information to project future demand. The SCM then created a shipment timeline for the priority countries, determining when and where enrolment would need to be halted.

Almac's situation analysis revealed that the expected replacement shipment would, in fact, support an additional 50-100 patients, and that enrolment could be accelerated in three countries.

Almac also recommended changes in the resupply strategies for individual sites so that shipments were sent less frequently in order to minimise the cost and risk of shipping frozen vials.

The client results:

Accelerated enrolment closes trial one month ahead of schedule

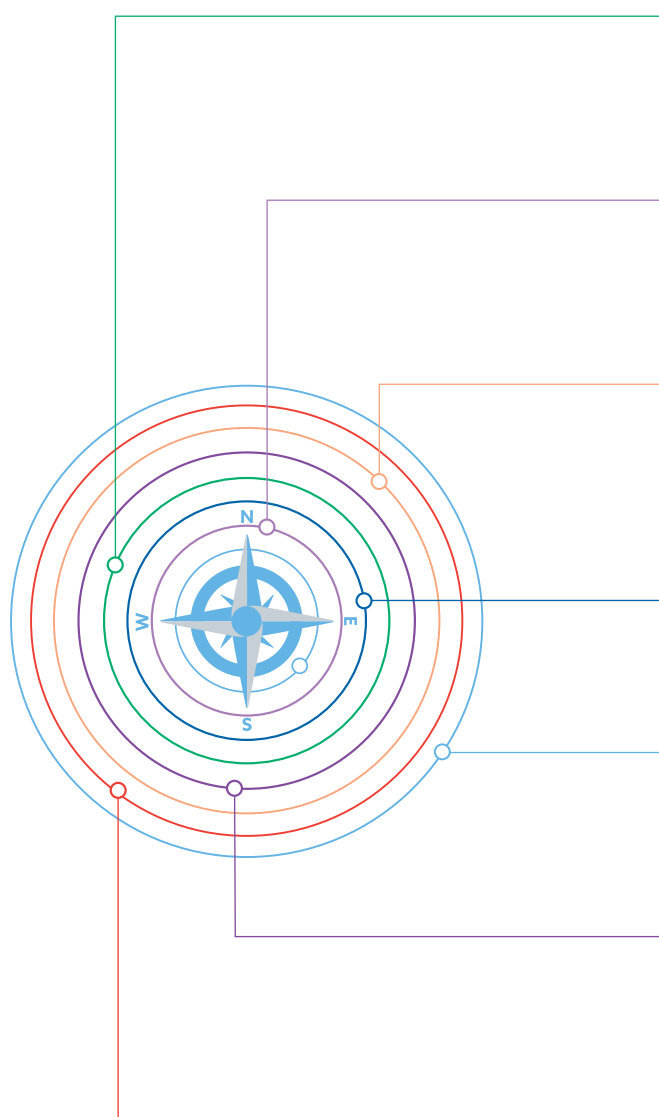
Thanks to Almac's intervention, the sponsor's clinical operations team's fears were avoided. There was no need to halt enrolment. By carefully apportioning existing supplies according to Almac's plan, the sponsor was able to continue the trial uninterrupted; - continuity that was important in preserving the sponsor's relationships with sites and to keeping the development timeline on track.

Almac's new supply plan prevented a break in the trial, allowed for accelerated enrolment, and reduced overall shipping costs. As a result, the trial closed a full month early, which translated into operational savings as well as the potential to reach the market sooner.

The sponsor has continued to partner with Almac's supply chain group on other clinical studies.

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.

Inventory management

SCMs 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.

IRT Medication management

SCMs 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.

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.

Temperature management solutions

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

Bulk drug management

SCMs 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.

Other services

Almac SCMs 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.

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