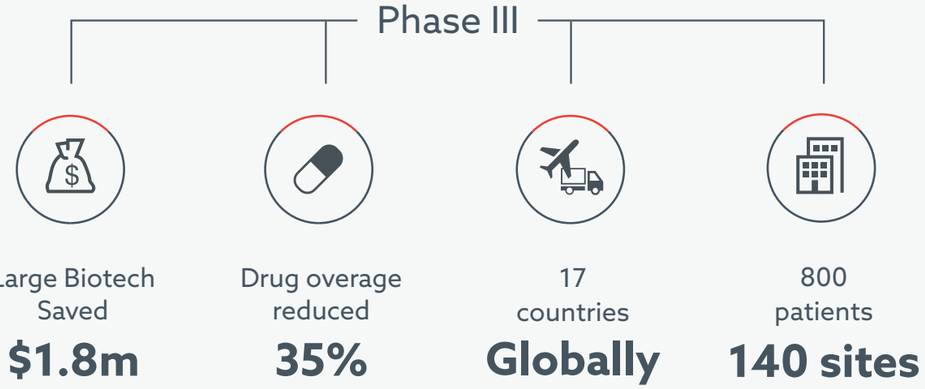
ALMAC

Partnering to Advance Human Health

Case study

Large biotech makes cost savings of $1.8 million phase III study

Large biotech makes cost savings of $1.8 million in Phase III study by engaging Almac's Supply Chain Management expertise to manage the drug supply for a high value biological product.



BACKGROUND

A large biotech company, was planning a multinational, phase III trial involving 800 patients to compare the efficacy, safety and tolerability of the Investigational Medicinal Product (IMP) with a comparator drug product for the treatment of Multiple Sclerosis.

One hospital recently found itself in this exact situation. The To eliminate bias, the study was designed to be a randomised, double-blinded, placebo-controlled, parallel group equivalence trial, conducted in 17 countries involving 140 sites located in Western Europe, Russia, Ukraine, United States, Latin America and South Africa. Study participants were randomly assigned to receive IMP, comparator or a placebo for 9 months, followed by open label treatment for 15 months.

The sponsor company approached Almac to provide the following services throughout the duration of the study:

- Forecasting and Supply Chain Management Services
- Development of Master English Text
- Comparator Procurement
- Packaging, Distribution and Depot Services
- QP Release

The business challenges

Comparator supply

- The lead time for the procurement of the comparator drug was 12 weeks; the product was expensive and had a typical shelf life of 18 months upon receipt. This had significant implications for overall supply utilisation as a blinded expiry date was applied across three treatment groups.
- There was limited availability of stability data to support decisions on temperature excursions for shipments containing comparator product.

IMP and Placebo Supply

A third party, contract manufacturer was responsible for the manufacture of IMP and placebo – during the study there were several critical issues with this supply resulting in significant disruption to the bulk supply chain.

The Almac solution

The main priority of Almac's Supply Chain Manager was to ensure continuity of supply for patients already entered into the trial and then to ensure IMP was available to support new patients at all stocking points in the supply chain.

In response to the issues with IMP supply, comparator availability, cost and lead time, the Supply Chain Manager conducted an in-depth review of site level inventory against actual recruitment and projected recruitment figures and compared these to the Interactive Response Technology (IRT) ordering parameters. Based on the IRT analysis the Supply Chain Manager made the following observations:

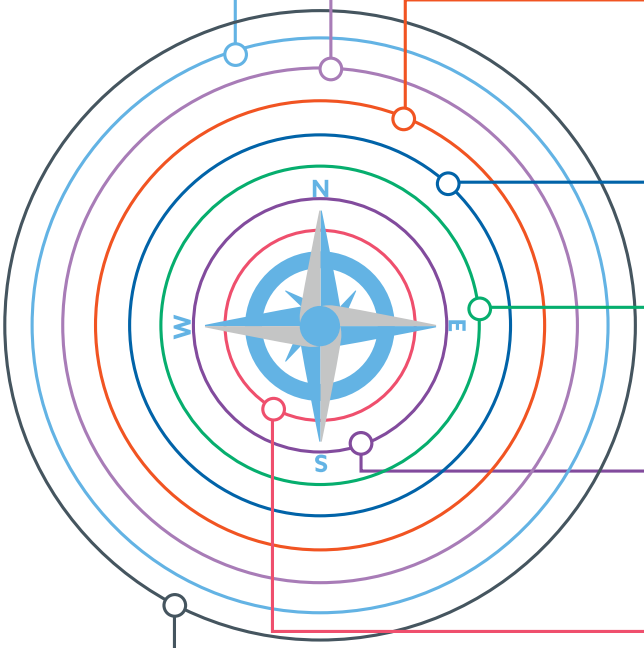
- The time between dispensing kits varied; ranging from 35–91 days.
- The system was designed with the standard IRT functionality; the system stopped dispensing kits based on the longest visit window - 91 days. As a result, there were many kits not being selected during other visits when they could have been used, leading to high wastage.
- The Supply Chain Manager proposed that the IRT be amended to consider visit duration when determining when kits should not be assigned. In addition, to ensure continuity of supply, the Supply Chain Manager initiated a process in conjunction with the IRT and the Contract Research Organisation (CRO) to review site requirements, determining when and where orders should be raised, based on existing patients and screened patients that had been confirmed eligible. This resulted in an immediate reduction in drug supply levels, both initial and resupply.
- Throughout the study duration, the Supply Chain Manager performed an ongoing assessment of projected recruitment and enroled patient need, linking that to kit placement (sites and depots) to enable quick decisions on patient enrolment. This resulted in smaller, more frequent shipments but less wastage and minimised the risk of stock-outs.

The results

- As a result of dedicated Supply Chain Manager oversight of the study, Almac was able to ensure patient recruitment could continue and study timelines were met.
- $660,000 saved via the dispensing of >700 kits that otherwise would have remained unused prior to adjustments to the IRT. The adjustment recommended by the Supply Chain Manager cost only $6,600 to implement.
- An additional $1,138,500 saved in comparator procurement costs following the proposal of reduction in overage from 60% to 25% prior to completion of enrolment.
- $660,000 saved via the dispensing of >700 kits together $1,138,500 saved in comparator procurement costs for an overall savings of $1.8 million.

"The role of Almac's Supply Chain Manager in this trial was critical to overcoming the challenges with IMP supply and to ensure continued treatment and recruitment of new patients. As a trusted partner, we believe Almac's quality, reliability, flexibility and strong communication contributed significantly to successfully meeting our study timelines."

Head of Clinical Operations



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

Almac 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

Almac 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 Services

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.

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.

Investigator Initiated Trials and Specialised Clinical Programs

Almac SCMs can provide full end-to-end planning, design and management of the clinical supply chain for Investigator Initiated Trials, Expanded Access and Named Patient Programs, designing flexible supply solutions and working directly with clinical sites where necessary to ensure continuous supply.

Pharmacy Services

Almac SCMs can serve as unblinded contacts for drug management and reconciliation, eliminating the need for additional unblinded site monitoring staff. We also have licensed pharmacists who can write pharmacy manuals, dose cards, patient and investigator educational materials; as well as provide input to clinical materials sections of trial protocols. These pharmacists can provide site personnel training at investigator meetings and can be on-call for dosing and drug compatibility questions throughout the trial.

almacgroup.com

GET IN TOUCH

Global HQ
+44 28 3836 2436

US HQ
+1 215 660 8500

Asia HQ
+65 6309 0720

EU HQ
+353 42 932 0718

Souderton PA USA
+1 (215) 660-8520

Japan
+81 367 218720

clinicalservices@almacgroup.com

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