

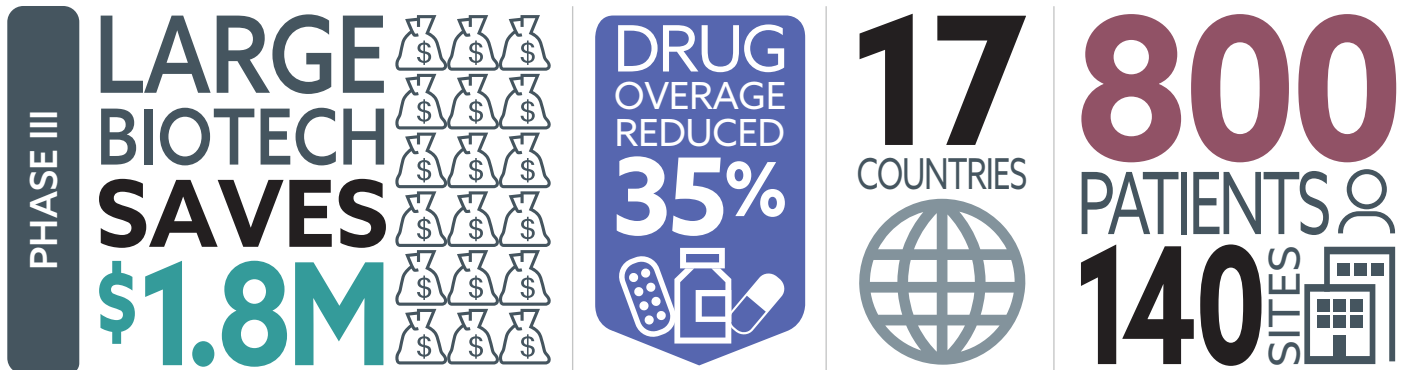


CASE STUDY

LARGE BIOTECH MAKES COST SAVINGS OF \$1.8 MILLION IN 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

Our client, 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.

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

CHALLENGES FACED

There were a number of challenges Almac faced throughout this study.

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.

“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

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.

ALMAC APPROACH

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 SCM 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 SCM 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 SCM 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 SCM 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 SCM performed an ongoing assessment of projected recruitment and enrolled 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.

RESULTS

- As a result of dedicated SCM 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 SCM 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.

All our clients have unique needs.
That's why we develop unique solutions.

This is the **ALMACTOUCH™**



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