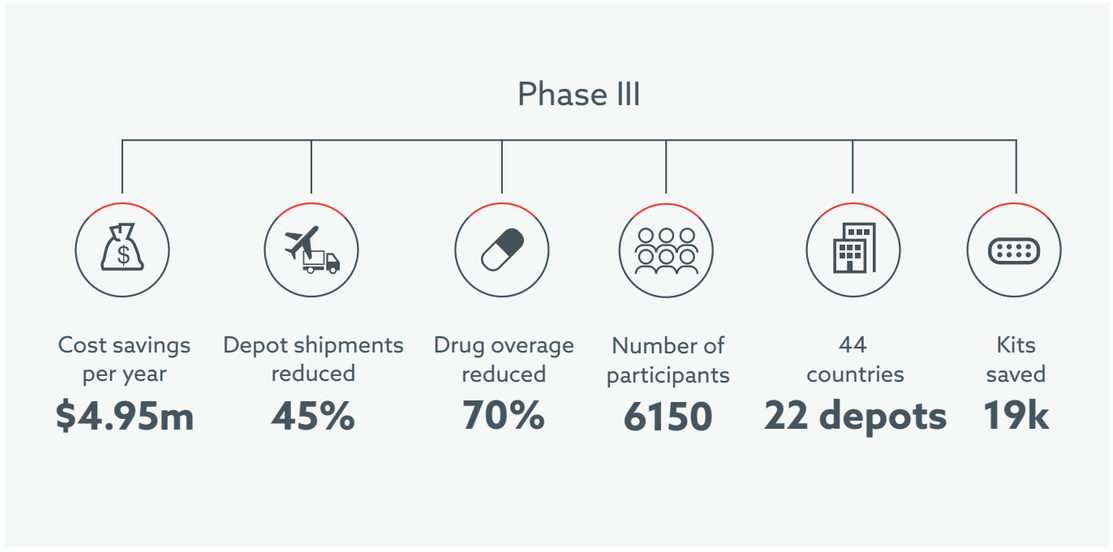
ALMAC

Partnering to Advance Human Health

Case study

$5M Saved for Top 20 Global Pharma Company with Almac Supply Chain Oversight

Top 20 global pharma company makes cost savings of almost $5million per year in Phase III study from utilising Almac's Supply Chain Management expertise mid-trial.



BACKGROUND

Top 20 global, pharmaceutical companies was conducting a phase III trial to compare the efficacy, safety, and tolerability of multiple doses of Investigational Medicinal Product (IMP) with a comparator drug product for the treatment of Diabetes.

The study was a randomised, double-blinded, parallel group trial. This was a global phase III trial with 44 countries participating across Europe, United States, Latin America, Asia and Africa.

The sample size was 6,150 and participants were randomly assigned to receive IMP or comparator, with each patient to be treated for a period of 7 years. The total duration of the study from First Patient In to study completion was 9 years.

Titration study IMP Arm had 4 possible dose strengths and patients were able to titrate up and down at any visit.

The sponsor company had initially contracted Almac to undertake the packaging, global distribution, and Interactive Response Technology (IRT) for the study, retaining responsibility for Qualified Person (QP) release, forecasting and Supply Chain Management (SCM) services.

After 18 months the client asked Almac to provide SCM services which included forecasting and inventory management in addition to those already contracted.

The business challenges

There were a number of significant challenges to maintain and optimise the IMP supply chain:

- 22 local depots were being used, reducing the flexibility of the overall supply.
- The shelf life of the IMP could not be extended.
- Patients were randomised centrally, all kit types were required to be included in initial site shipments as it was not possible to predict randomisation at the site.
- The protocol design allowed patients to dose maintain, reduce or escalate throughout the study duration, this made it challenging in forecasting projected usage and associated demand across patients randomised into the study and having suitable inventory in place to meet demand. As a result of these challenges there were several stock outs and forced randomisations.
- To support the protocol defined variability in dose selection and ongoing titration the client had initially adopted a manufacturing strategy of applying 100% overage for all IMP dose strengths with production campaigns twice yearly. This resulted in a high percentage of kits remaining unused prior to expiration.
- The import license planning process was extremely difficult as there were several countries with long approval lead times and lack of visibility of demand per country resulted in frequent depot shipments.
- Information required by the Supply Chain Manager (SCM) to assess the supply chain was not readily available from the standard IRT reports.
- There were multiple expiry date events to be planned.

The Almac solution

The SCM assigned to the study conducted a full review of historical patient event data from the IRT reports.

This identified trends in dose titrations from patients enroled in the study. The SCM extrapolated to future visits of existing patients and for projected patients and recommended that the manufacturing strategy be adjusted to reflect these trends with overage being reduced to 30% plus site reseeding for expiry date events.

A comprehensive demand forecast of patient need was generated compared to depot inventory allowing the SCM to accurately predict quantities and timing for production campaigns and depot shipments.

The SCM identified the need for and format of a customised clinical and supply data transfer from the IRT. This was put in place and significantly reduced the time required to update the forecast on a monthly basis.

The SCM continued to monitor trends and update the demand forecast and associated production and distribution strategies accordingly.

The SCM initiated changes in IRT depot resupply parameters accordingly.

Figure 1: Supply Chain Assessment (Kits Produced)

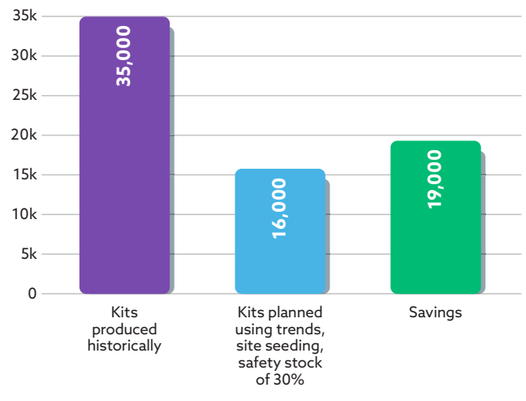
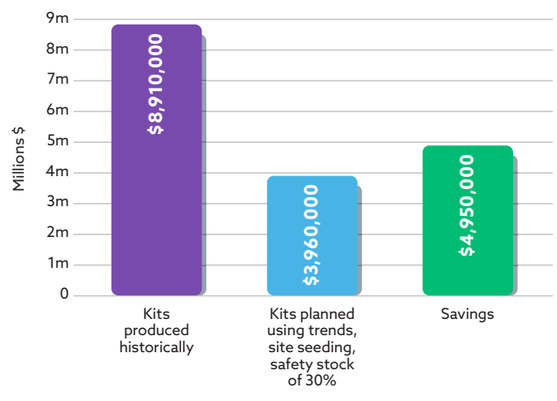


Figure 2: Supply Chain Assessment (Manufacturing & Shipment Costs)



The results

The client accepted the Almac SCM recommendations and this has led to cost savings of $4,950,000 per year in manufacturing and shipment costs – based on the historical quantities for one of the treatment arms - 35,000 planned vs. 16,000 - saved 19,000 kits.

- $4,455,000 (planned) vs. $1,980,000 = $2,475,000 savings every 6 months.
- Depot shipments have been reduced (45%) from approximately 45 per year to 25 per year.
- Forced randomisations and stock outs have been eliminated by the intelligent positioning of inventory and all stocking points in the supply chain.

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