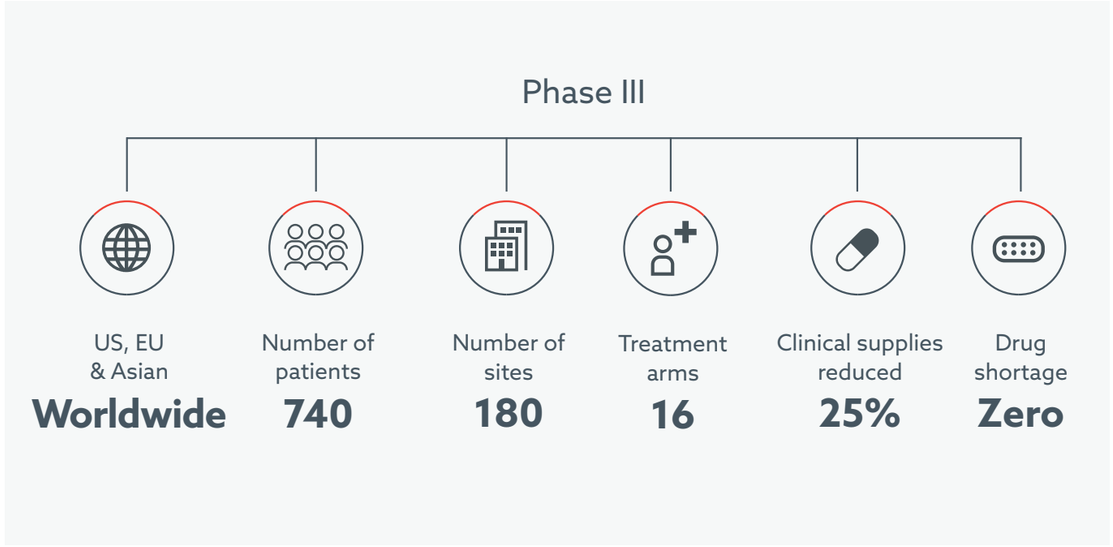
ALMAC

Partnering to Advance Human Health

Case study

Top Global CRO Advised by Almac's Supply Chain Management Team

Almac's Supply Chain Management team oversight helps a top global CRO client optimise the drug supply for a study sponsor based in Asia running 3 phase II studies in the EU, US and Asia.



BACKGROUND

A top global Contract Research Organisation (CRO), approached Almac to provide Supply Chain Management (SCM)which included forecasting and drug supply management for a small, pharmaceutical company based in Asia running three, phase II clinical trials.

All studies were double-blinded, placebo-controlled, metabolic studies to compare the efficacy of different doses of the sponsors Investigational Medicinal Product (IMP) in different subject populations. All 3 studies were conducted within 8 countries located in the US, EU and Asia.

The studies each enroled between 200-300 subjects at 40-100 sites, and had 4-8 treatment arms.

Almac generated the bulk drug and packaged supply requirement forecasts to enable the sponsor to plan their manufacturing schedules and Almac to plan their production and distribution needs. The Supply Chain Manger (SCM) was also responsible for the Interactive Response Technology (IRT) set-up to ensure the medication management strategies were aligned with the packaging and distribution approaches.

The business challenges

Due to the sponsor's limited production capacity there was limited IMP available for study start-up. The IMP was a combination drug with device. The use of the device was unclear. Almac and our client had to seek further clarification around the mechanics of the device.

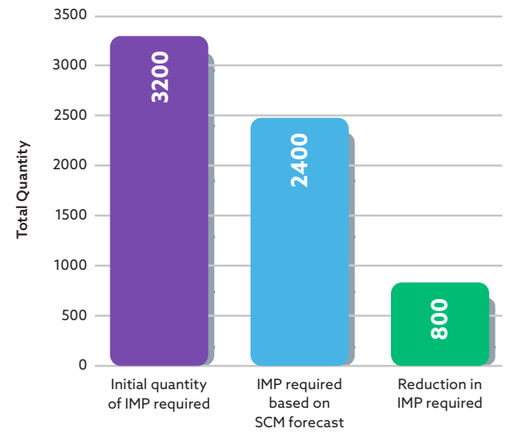
After initial quantities had been packaged and released and two of the three studies had commenced recruiting, an issue was identified with the second delivery of IMP resulting in additional inspections and a reduction in the available IMP for labelling and packaging. This meant the trial was at a high risk of having to stop as supply was unable to be released to meet patient demand.

The Almac solution

The Almac SCM reviewed the client's packaging designs in conjunction with the protocol and proposed a number of changes with the focus being on minimising the drug requirements.

The packaging designs were changed for 2 of the protocols. The number of different pack types were reduced, which streamlined the production operations and reduced costs. The new strategy enabled all packs to utilise the same cartons, inserts and label text. This led to some cost savings and a simplification in the IRT set-up. The changes also reduced the quantity of IMP required at site start-up by 25%.

Figure 1: Supply Chain Assessment (IMP Produced)



Clinical forecasting

The Almac SCM reviewed the study timelines, site activation schedules and predicted randomisations for each region for all 3 studies. Utilising Almac's clinical forecasting solution – SupplyWise™, the SCM proposed the optimum packaging quantities of each pack type per study as well as providing the sponsor and packaging facility with a forecast for the outstanding IMP delivery timing and quantities.

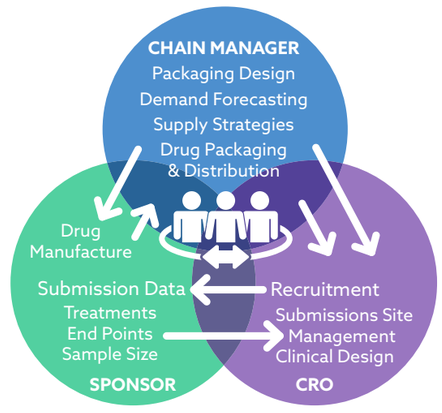
Change management

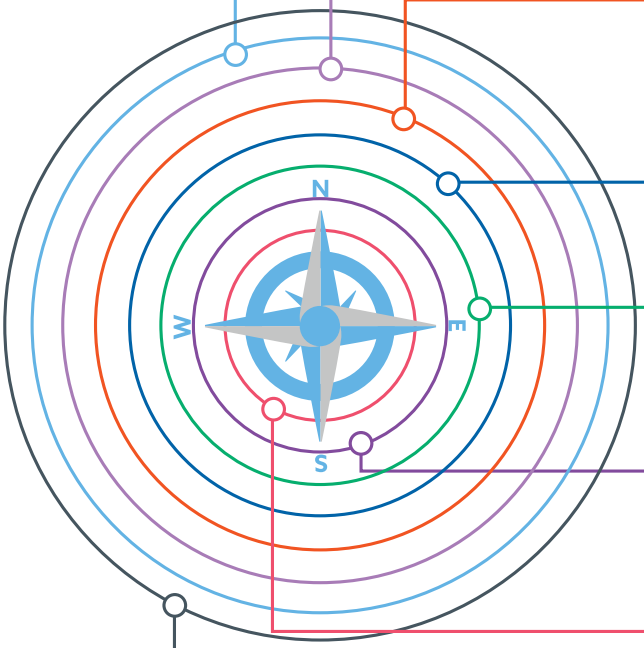
After initial quantities had been packaged and released and 2 of the 3 studies had commenced recruiting, an issue was identified with the second delivery of IMP. Almac's Qualified Person (QP) team worked continuously with the client for 3 weeks to resolve the issue.

The role of the SCM overseeing the study was critical as their knowledge of the packaging and distribution timelines enabled them to amend the proposed re-supply packaging quantities and prioritise the operations, to minimise the potential for drug shortages in the ongoing trials. Alongside the proactive SCM managing the study, Almac's global capacity and flexibility meant they were able to revise production schedules to meet the new timelines.

The results

- As a result of Almac's SCM oversight the CRO and sponsor were able to ensure study timelines were met and there were no drug shortages at any of the clinical sites.
- Re-design of the proposed patient packs by the Almac SCM resulted in a 25% decrease in the quantity of IMP to be manufactured for the 3 Phase II trials. This minimised drug wastage, saving the client money.





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.

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